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FDA Executive Summary

General Issues Panel Meeting on Germicidal Ultraviolet (GUV) Devices

Prepared for the Meeting of the General Hospital and Personal Use Devices Advisory Committee Panel

December 10, 2025

Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Food and Drug Administration

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Executive Summary for UV Germicidal Devices Panel

Section I - Introduction and Background

CDRH is committed to protecting public health and is organizing this Advisory Committee (Panel) meeting to fulfill a requirement under the Food and Drug Omnibus Reform Act of 2022 (FDORA) related to devices used in pandemic preparedness and to exchange knowledge with patients, providers, and manufacturers regarding the benefits and safety risks associated with the usage of Germicidal Ultraviolet (GUV) medical devices. GUV devices are products intended to transfer electromagnetic energy from a lamp source to generate ultraviolet radiation to a microorganism, penetrating the cell wall and destroying its ability to reproduce through a physical process. These products typically generate ultraviolet radiation over a light band range of 200-400 nm, which is conventionally divided into UV-A (315-400 nm), UV-B (280-315 nm), and UV-C (200-280 nm). The majority of germicidal devices operate in the UV-C range because these wavelengths have been demonstrated to be highly effective at microbial inactivation [3]. These products are considered medical devices when their intended use meets the FDA definition of a medical device, as defined in Section 201(h)(1) of the Federal Food, Drug, and Cosmetic (FD&C) Act. Per the FD&C Act, a medical device is defined as:

> *An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:*
>
> *A. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,*
> *B. 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*
> *C. 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).*

For example, Germicidal UV devices intended for use as an adjunct to manual cleaning of medical device surfaces or a chamber-based UV disinfection device intended to disinfect medical devices in health care environments (hospitals, day clinics, dental office, hospice, and other locations where medical devices may be exposed) would be considered medical devices. FDA has jurisdiction over devices that are intended to reprocess other medical devices or when exposure of other medical devices to UV radiation is expected. When medical devices are exposed to UV radiation without the proper evaluation of compatibility, safety, and effectiveness, the UV exposure may result in damage to the medical device, expose the end-user to harmful radiation leading to skin damage, eye damage, respiratory issues, or result in an ineffective germicidal endpoint.

Manufacturers of Germicidal UV devices must also comply with the Electronic Product Radiation Control (EPRC) provisions of the FD&C Act. EPRC protects the public from hazardous and unnecessary radiation exposure of radiation-emitting electronic products and covers a wide range of products including medical devices such as diagnostic x-ray equipment, ultrasound imaging devices, laser surgical devices, UV disinfection chambers, and whole room microbial reduction devices, as well as non-medical consumer products such as microwave ovens, televisions, and entertainment lasers. EPRC requirements

are defined in the FD&C Act (Chapter C, Subpart C) and 21 CFR 1000-1050. Manufacturers are responsible for producing products that comply with these requirements.

Regulatory History of GUV Devices

Prior to the onset of the COVID-19 public health emergency (PHE)[1] in 2020, the regulation of GUV medical devices was limited to the following classification regulations, in addition to the established EPRC requirements:

- 21 CFR 880.6500 (Medical ultraviolet air purifier);
- 21 CFR 880.6600 (Ultraviolet (UV) radiation chamber disinfection device); and
- 21 CFR 880.6710[2] (Medical ultraviolet water purifier).

The usage of these products in a healthcare environment was not widespread and there were only a small number of devices submitted for premarket review utilizing this technology prior to the PHE.

Following the onset of the PHE, the Agency noted an increased interest in the usage of GUV technology, particularly in healthcare environments. In addition to Emergency Use Authorization (EUA) [3] requests for UV-based technologies intended to reprocess Personal Protective Equipment (PPE), other innovations such as "whole room UV disinfection devices" started gaining more widespread usage. This technology was largely associated with the application of whole room microbial reduction, which was being marketed for "disinfection" or "pathogen reduction" of various environments in a healthcare facility. While the usage of GUV may result in a reduction of pathogen load, the actual microbicidal reduction performance, impact on other medical devices or its clinical relevance to support routine hospital or reprocessing applications had yet to be demonstrated at that time. To meet a public health need for increased availability of reprocessing solutions, FDA sought to exercise selected, safety-focused regulatory flexibilities that did specifically impact UV air purifiers and UV-based disinfection devices, among other disinfection and sterilization devices. This policy was reflected in the FDA Guidance document "*Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*", which specifically addressed UV decontamination systems and included the applicability of UV technology as an adjunct to currently existing practices, as well as in disinfectant devices or air purifiers. This policy remained in effect only for the duration of the PHE and expired on November 7, 2023.

Since the PHE, there has been ongoing growth in the GUV space related to applications in microbial reduction or disinfection claims. The FDA has continued to build on earlier groundwork for the regulatory oversight of UV medical devices, as we continue to see larger numbers of products entering the healthcare environment, with new and expanding intended uses. The Agency has remained engaged in furthering the advancement of technical applications for GUV, for example, establishing additional

[1] See Coronavirus (COVID-19) and Medical Devices | FDA for additional information.

[2] Devices classified under 21 CFR 880.6710 are exempt from premarket notification (510(k)) subject to the limitations in 21 CFR 880.9.

[3] For more information on COVID-19 Emergency Use Authorizations for Medical Devices see COVID-19 Emergency Use Authorizations for Medical Devices | FDA. For information regarding FDA's emergency use authorities under section 564 of the FD&C Act, see the guidance "Emergency Use Authorization of Medical Products and Related Authorities" ("EUA Guidance"), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities

classification regulations for Whole Room Microbial Reduction Devices under 21 CFR 880.6510[4] and UV Radiation Disinfection Chamber Devices under 21 CFR 880.6511[5].

Purpose of Meeting:
With continued innovation in GUV medical device technologies, the Agency has prioritized developing clear, consistent, scientifically sound approaches to regulate GUV devices. The purpose of this AC meeting is to deliberate and obtain input related to germicidal ultraviolet light as a mode of disinfection. FDA is seeking feedback to improve the total product lifecycle (TPLC) evaluation of GUV disinfection devices. This includes, but is not limited to, discussions around manufacturer and end user perspectives, performance testing, study design considerations, and antimicrobial stewardship. In addition, the Panel will discuss and provide advice to FDA on these devices used in pandemic preparedness, to satisfy, in part, a requirement under the Food and Drug Omnibus Reform Act of 2022 (FDORA).

Specifically, the Agency will be seeking feedback on:

- What recommendations does the Panel have for performance testing specific to UV radiation reprocessing that may support a standalone disinfection intended use?
- What study design considerations should be used to support indications for Healthcare-Associated Infection (HAI) reduction or prevention?
- What information would be needed to support a general hierarchy of resistance for UV that could be applied across the device type?
- What susceptibility testing, exposure limitations, and review aspects should be considered to support antimicrobial stewardship and guard against UV resistance? How could these medical devices be used with existing practices to mitigate the rise of UV resistance?
- What information is helpful to healthcare providers to promote transparency and improve comprehension for the intended uses for which these technologies are currently authorized?
- What other considerations for germicidal UV reprocessing innovations should CDRH focus on for pandemic preparedness or routine healthcare use?

Section II - Overview of Medical Device Reprocessing

Cleaning, microbial reduction, disinfection, sterilization – Definitions and Terminology

Germicidal UV may be used to reprocess reusable medical devices. Collectively referred to as reprocessing, each reprocessing step is implemented to achieve a specific end point and return a medical device to suitable condition for reuse on the same or another patient. For this reason, cleaning steps should be validated separately and independently from disinfection or sterilization steps. As per 21 CFR 820.30, manufacturers of class II, or III and most class I devices are required to establish and maintain procedures to control the design of their device in order to ensure that specified design requirements are met and are subject to design controls. For devices that are subject to design controls under 21 CFR

[4] This classification regulation includes special controls established in the classification order, available at DEN230007.Letter.DENG.pdf. The publication of this classification in the Federal Register and codification in the Code of Federal Regulations is currently pending.
[5] This classification regulation includes special controls established in the classification order, available at DEN230067.Letter.DENG.pdf. The publication of this classification in the Federal Register and codification in the Code of Federal Regulations is currently pending.

820.30, the device design, including its labeling such as reprocessing instructions, are expected to be validated.

For certain reusable medical device premarket submissions, including Premarket Approval (PMA) applications, Humanitarian Device Exemption (HDE) applications, De Novo requests, and 510(k) submissions for certain device product codes, FDA expects submission of complete validation testing to support the proposed reprocessing instructions. As identified in FDA's Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling[6]" (Reprocessing Guidance Document) Appendix E, only submissions for reusable devices for certain regulations and product codes are expected to contain data such as protocols and complete test reports to support validation of reprocessing instructions. Additional considerations for devices subject to 510(k) requirements may be communicated in device specific guidance documents or requirements in classification regulations (i.e., special controls) which may indicate submission of validation documentation is needed. In general, expectations for submission of complete validation data may be influenced by the risk or likelihood of microbiological contamination based on the intended use and reuse conditions of the reusable medical device.

In addition to validation data, reprocessing instructions for use in the labeling should be:

- Easy to understand,
- Technically feasible and comprehensive,
- Advise the user to thoroughly clean the device, and
- Indicate the appropriate downstream microbicidal process for the device (e.g., disinfection or sterilization).

An important aspect of the intended use that should be considered for reprocessing validation is the location (i.e., environment of use) where the reusable medical device is intended to be used.

The Spaulding Classification [11] is established to support determination of the appropriate level of reprocessing; inclusive of cleaning, disinfection, and/or sterilization of the medical device. According to the Spaulding classification, the nature of medical devices should be categorized as critical, semi-critical and non-critical according to the degree of risk for infection involved in use of the products. The following classification levels are identified [1,10]:

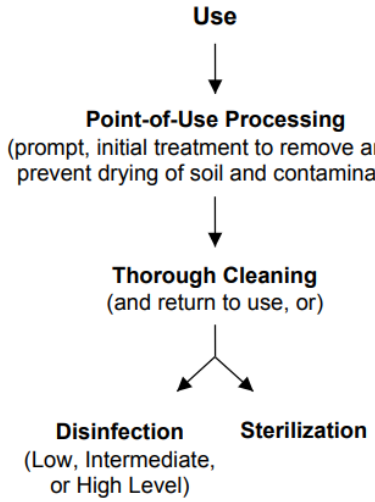
a. ***Critical Devices***. *Critical devices are devices that are introduced directly into the bloodstream, or which contact a normally sterile tissue or body-space during use. There is a likelihood of microbial transmission and risk of infection (subclinical or clinical) if the device is not sterile. Critical devices are reprocessed by sterilization between uses.*

b. ***Semi-Critical Devices***. *Semi-critical devices are devices that contact intact mucous membranes or non-intact skin. They do not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body. Intact mucosal surfaces are relatively resistant to small numbers of spores. However, these devices should be reprocessed to be free from all microorganisms. Semi-critical devices are reprocessed by sterilization or alternatively high-level disinfection (HLD) between uses.*

[6] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.

c. ***Non-Critical Devices***. *Non-critical devices are instruments and other devices whose surfaces contact only intact skin and do not penetrate it. Non-critical devices also include devices that do not directly contact the patient but may become contaminated with microorganisms and organic soil during patient care (e.g., blood, body fluids); such devices may not be visibly contaminated. FDA recommends thorough cleaning, then intermediate or low-level disinfection for non-critical devices depending on the nature and extent of contamination between uses.*

An overview of medical device reprocessing is found in FDA's Reprocessing Guidance Document as shown below.



Additionally, the following definitions are applicable to the current model established for reprocessing of medical devices. Note that the following definitions are general to medical device reprocessing and not specific to the application of UV technology.

- "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."

- "Point-of-Use Processing: Reprocessing begins with processing at the point of use (i.e., close proximity to the point of use of the device), to facilitate subsequent cleaning steps." This includes prompt, initial cleaning steps and/or measures to prevent drying of soil and contaminants in and on the device.

- "Cleaning: Physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use." Effective cleaning should minimize the soil transfer from one patient to another or between uses in a single patient; prevent accumulation of residual soil throughout the medical device's use life; and allow for successful, subsequent disinfection or sterilization steps. Cleaning procedure will vary depending on the complexity of the device (see

Table 2 in Reprocessing Guidance Document for examples of design features that may pose a challenge to adequate reprocessing)."

- "Disinfection: A process that destroys pathogens and other microorganisms by physical or chemical means," which are further subcategorized as high-level disinfection (HLD), intermediate level disinfection (ILD) and low level disinfection (LLD). This is achieved through exposure to a "Disinfectant: An agent that destroys pathogenic and other kinds of microorganisms by chemical or physical means. A disinfectant destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores."

- "High Level Disinfection: 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."

- "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."

- "Sterile: State of being free from viable microorganisms."

Section III – GUV Microbicidal Properties and Current Clinical Practice

Microbicidal Properties – Mechanisms of Action:

Technologies used for reprocessing of medical devices may utilize various physical or chemical methods to achieve their endpoints. Detergents are commonly used for cleaning, and there are a variety of liquid chemical germicides used to achieve disinfection or sterilization. UV radiation, specifically UV-C, has begun to emerge as an increasingly prevalent alternative to the established reprocessing techniques. Ultraviolet-C radiation has potent germicidal properties, with peak microbicidal effectiveness in the 250–270 nm range [2] UV-C photons are strongly absorbed by microbial genetic material, inducing molecular damage such as the formation of cyclobutane pyrimidine dimers in DNA (and analogous lesions in RNA). These abnormal intra-strand bonds distort the nucleic acid structure and block essential processes like replication and transcription, rendering microorganisms incapable of reproduction [3]. This in situ destruction of nucleic acids underlies UV-C's lethality against bacteria, viruses, and fungi. Notably, susceptibility varies by organism: vegetative bacteria and many viruses are inactivated at relatively lower doses compared to bacterial or fungal spores which are considerably more UV-resistant and require much higher or longer UV exposure to achieve kill [2]. In general, achieving a microbicidal effect with UV-C requires delivering a sufficient dose (fluence) of UV energy to the target microbes. The Panel will be asked to provide input on what information would be important to support a general hierarchy of resistance for UV.

A primary limitation of UV-C is its line-of-sight requirement—only directly illuminated surfaces are subject to microbial reduction, leaving shaded or obstructed areas untreated. This can create challenges for medical device reprocessing, particularly in equipment crevices or under debris, such as patient soil. UV-C cannot penetrate or work through organic matter, so dirt or biological residues can shield microbes,

making thorough cleaning essential before UV treatment [4]. Variability in UV dose delivery, due to factors like distance and surface angles, can result in uneven microbial reduction. This technology only treats surfaces that are directly illuminated. Unlike liquid disinfectants, GUV does not penetrate lumens or porous materials. Therefore, usage of UV as a microbicidal agent should be implemented carefully to minimize shadowing effects, and optimize lamp placement and exposure times, with an understanding that only directly illuminated areas are reliably treated and some items may require supplemental methods. The Panel will be asked to advise on UV-specific performance testing that may support specific intended uses, such as standalone disinfection.

Microorganisms possess natural defense mechanisms that enable them to repair DNA damage caused by UV exposure. Notably, processes such as photoreactivation—where visible light activates enzymes to directly reverse UV-induced DNA lesions—and dark repair mechanisms like nucleotide excision repair allow microbes to recover from sub-lethal doses if given the right conditions. Therefore, if UV disinfection is performed at inadequate doses or under suboptimal environmental conditions, some microbes may survive, repair damage, and potentially regain viability. This underscores the necessity of delivering a sufficient UV dose and, when possible, minimizing exposure of treated items to visible light immediately after disinfection to prevent photoreactivation [5].

From an antimicrobial resistance perspective, it is theoretically possible that extensive and repeated use of UV in hospital settings could create selective pressure that favors the survival of organisms with traits such as spore formation, enhanced DNA repair mechanisms, or pigmented cell walls [6]. Over-reliance on UV devices could lead to a predominance of more UV-tolerant organisms, causing concerns of clinical pathogens developing true "UV-C resistance" comparable to antibiotic resistance. This situation would be similar to the way overuse of any antimicrobial can promote the selection of harder-to-eliminate microbes. Therefore, it may be prudent to avoid suboptimal, low-dose UV-C use to minimize the risk of fostering UV-tolerant microbial populations. Panel advice will be requested regarding implementation of antimicrobial stewardship for GUV.

Current Clinical Practice/Hospital Practices for Reprocessing:

The use of Germicidal UV medical devices in clinical healthcare settings is a relatively recent and rapidly expanding area of clinical use. Presently, there are several clinical areas where advances in GUV technology are being applied including applications in air purification, adjunctive microbial reduction, and disinfection of smaller reusable medical devices.

Clinical Benefits

GUV technology produces non-ionizing radiation to achieve microbial reduction or disinfection in multiple use applications. Traditional cleaning or disinfection methods often utilize harsh chemicals that may be hazardous to users and have the potential to leave harmful residues that may present risks to patients. This may represent an area of benefit for the use of GUV over traditional chemical disinfection as GUV radiation does not leave chemical residues on medical devices [4]. Additionally, the FDA is aware there may exist an increased human error rate in reprocessing units due to the increasing complexity of devices and manufacturers' instructions for cleaning and disinfection. The use of appropriately validated, automated GUV devices may provide for a more standardized microbial reduction process when used as an adjunct to the complex and labor-intensive manual disinfection

processes associated with chemical disinfectants. Automated germicidal UVC, if safely accomplished, could provide an automated option which may lower the reprocessing error rate for some situations.

Clinical Risks

Since these devices generate UV radiation to support a microbial reduction or disinfection process, the risks associated with usage of these medical devices in a healthcare or medical environment should be adequately mitigated. The FDA has identified the following safety concerns for these medical devices as presented below.

- **Material Compatibility**: The risk of UV radiation exposure to medical device surfaces may impact functionality as a result of material incompatibility. GUV exposure has been shown to result in the degradation of some device components, especially plastics, rubber and fabrics, over time [7]. Material compatibility testing is important to maintaining device integrity for user and patient safety.
- **Risk of UV Exposure**: There are potential health and safety risks associated with UV radiation exposure, including burn damage to skin and eyes, respiratory challenges, delayed cancers (e.g. basal cell, squamous cell, melanoma), cataracts, and macular degeneration. UV light exposure risks can increase in the presence of photosensitizing medications, certain skin conditions and genetic predispositions to UV sensitivity. Further, the reactive oxygen species byproducts, including ozone, of UV devices can present irritation and toxicity risks for any chronic user [4].
- **Unsupported Microbiological/Infection-related Claims**: It is important that microbiological and infection-related uses of GUV devices are appropriately substantiated and that GUV device labeling is truthful and accurate. FDA is aware of promotion of GUV devices that include unsubstantiated claims regarding the effectiveness of UV devices against specific diseases or an undemonstrated clinical benefit. GUV devices being marketed with such claims without FDA authorization may create uncertainty regarding the device's effectiveness against the broad spectrum of bacteria and viruses as claimed. This could potentially lead to adverse health outcomes to the patient and healthcare worker in a healthcare setting if a GUV device does not perform as intended.
- **Microbial Resistance Hierarchy:** The hierarchical profile of microbicidal effectiveness is different for UV radiation versus chemical disinfectants. For UV disinfection, pigmented fungal spores may be more resistant than the bacterial endospores typically considered most resistant to traditional liquid chemical germicides [9]. The FDA is concerned that the presence of fungal spores on semi-critical medical devices following UV disinfection creates an increased risk to the patient, especially in a vulnerable population (e.g., diabetic or immunocompromised patient).
- **Inadequate Device Performance**: GUV devices generate UV radiation to achieve microbial reduction of surfaces. However, the FDA also believes that UV as a germicide for medical device reprocessing has technological limitations such as shadowing and low penetration. While liquid chemical germicides can saturate a reprocessed device for broad coverage, GUV application is more limited to direct sites of exposure. These limitations may challenge the ability for manufacturers to support broad standalone disinfection claims with appropriate safety and effectiveness data, especially for reusable medical devices with complex geometries, materials of construction, and potential for contamination/soiling.

Section IV — Regulatory Landscape of Germicidal UV Medical Devices

The FDA has established distinct device classification regulations for GUV technology used for medical purposes (e.g., microbial reduction or medical device reprocessing in a medical or healthcare

environment). The following GUV device types are intended to achieve microbial reduction in healthcare settings or on other medical device surfaces and are considered to be devices as defined in Section 201(h) of the FD&C Act. Certain classification regulations establish special controls to mitigate risks to health and provide a reasonable assurance of safety and effectiveness. Products that are radiation-emitting are also subject to radiation safety regulations in 21 CFR 1000-1050.

- **Whole Room Microbial Reduction Device**: (21 CFR 880.6510) [7], 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. These devices are intended to reduce microbial load on non-porous, non-critical medical device surfaces as an adjunct following routine hospital cleaning and disinfection procedures. The devices are specifically indicated as adjuncts to manual reprocessing, including healthcare room cleaning and disinfection protocols, due to the inherent limitations of GUV technology, including line-of-sight requirements that leave shaded areas untreated, inability to penetrate organic matter or lumens, and variable dose delivery based on distance and surface angles. Unoccupied rooms are the intended environment of use for whole room microbial reduction devices. Their design includes redundant safety features to ensure safe operation without human presence, helping prevent accidental exposure to the UV light.

  Whole room microbial reduction devices are subject to special controls which provide a reasonable assurance of safety and effectiveness of the device type. The special controls require non-clinical performance testing demonstrating microbial log reduction using clinically relevant resistant microorganisms on representative medical device surfaces under simulated worst-case conditions (including soiling, room objects, and distances), in-use testing under real-world conditions, photobiological safety validation of lamp systems, and long-term material compatibility assessment on clinically relevant surfaces, among other requirements. Biocompatibility testing is also required to demonstrate safe residual levels of chemicals on medical devices surfaces and/or gaseous byproducts in air. These requirements address identified risks to health including exposure to UV radiation causing skin and eye damage, respiratory irritation from chemical byproducts like ozone, patient cross-contamination due to device failure leading to inadequate microbial reduction.

- **Ultraviolet Radiation Disinfection Chamber Device:** (21 CFR 880.6511) [8] Ultraviolet Radiation Disinfection Chamber Devices are 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. Ultraviolet radiation disinfection chamber devices achieve microbial reduction on surfaces of medical devices through the use of a UV-C germicidal source. These devices specifically target the surfaces of semi-critical medical devices, for example external (intact skin contacting), transvaginal and transrectal ultrasound probes. Their design includes redundant safety features to ensure safe operation such as door interlocks and other controls to ensure delivery of a minimum effective dose is achieved throughout the chamber.

[7] This classification regulation includes special controls established in the reclassification order, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN230007. The publication of this classification in the Federal Register and codification in the Code of Federal Regulations are currently pending.
[8] This classification regulation includes special controls established in the reclassification order, available athttps://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN230067. The publication of this classification in the Federal Register and codification in the Code of Federal Regulations are currently pending.

As part of the FDA medical device pre-market review process, ultraviolet radiation disinfection chamber devices are subject to special controls which provide a reasonable assurance of safety and effectiveness of the device type. Special controls require non-clinical performance testing including resistance testing to establish a hierarchy of UV resistance using clinically relevant and UV-resistant microorganisms, potency testing against bacterial spores, vegetative bacteria, mycobacteria, yeast/molds and viruses to achieve microbial log reduction of a panel of clinically relevant and UV resistant microorganisms appropriate for the intended level of disinfection. Simulated use testing under worst-case conditions with appropriate challenge microorganisms and residual soil as well as in-use testing under real-world clinical conditions are required to demonstrate device performance. To further support device safety, controls for biocompatibility, photobiological safety of lamp systems, features to prevent inadvertent UV exposure, and long-term material compatibility assessment following repeated UV disinfection cycles were also established. Together, these requirements address identified risks to health including patient cross-contamination due to device failure or operator error leading to inadequate microbial reduction, exposure to UV radiation causing skin and eye damage, material incompatibility of devices intended for disinfection leading to reduced performance or premature failure.

- **Medical Ultraviolet Air Purifier**: (21 CFR 880.6500) 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. Inactivating airborne microorganisms can be used as an adjunctive to existing hospital ventilation systems found in patient rooms and in operating rooms. Microbial reduction is achieved typically through the recirculation of air through an enclosed device containing a UV radiation source as the technical method. Performance of these devices is demonstrated for a set exposure duration, room volume and device operational settings.

  As part of the FDA medical device pre-market review process, the microbial reduction levels achieved for each device performance setting is evaluated. This typically includes parameters such as device setting (speed), duration of exposure and time to achieve the claimed log reduction of claimed microorganism. Medical ultraviolet air purifiers should generally demonstrate a minimum 4 log reduction to support device performance. Additionally, safety testing is conducted to support biocompatibility, device safety interlocks, photobiologic safety and validation of ozone generation within acceptable limits per 21 CFR 801.415[9] is conducted. Filtration performance, performance demonstrating effectiveness against representative bacterial species and viruses, as well as risk assessment for air flow impacts may be conducted, as appropriate.

- **Other UV Devices:** 21 CFR 880.6600 Ultraviolet (UV) radiation chamber disinfection devices and 21 CFR 880.6710 Medical ultraviolet water purifiers are additional classification regulations associated with Germicidal UV devices. 21 CFR 880.6600 covers UV chamber disinfection devices intended for low level disinfection only. 21 CFR 880.6710 covers UV water purifiers, which are class II devices exempt from 510(k) requirements, that are intended for medical purposes and are used to destroy bacteria in water by exposure to ultraviolet radiation.

[9] 21 CFR 801.415 relates to the maximum acceptable level of ozone and applies to UV disinfection devices. For some device types, this is assessed as part of the biocompatibility evaluation. For other device types, for example where the device is exposing the outside environment to UV, additional testing may be required.

Section V – Current Challenges for Germicidal UV

New technology considerations:

The emergence of novel UV-based germicidal devices has revealed significant gaps in test methods and knowledge that would benefit from further discussion. A key challenge is the lack of accepted standard test methods for UV-C devices. Most established protocols used to evaluate microbicidal performance, like Association of Official Analytical Collaboration International (AOAC) or American Society for Testing and Materials (ASTM) standards, were developed for liquid chemical disinfectants and may not be applicable to light-based technologies. For example, some of the established methods involve immersion of test substrates or inoculated medical devices directly into the liquid chemical germicide, which cannot be accomplished for UV exposure. Similarly, testing for liquid chemical germicides typically involves inoculating worst-case locations on reusable medical devices such as cracks, crevices, joints, or other hard-to-reach locations, which may be impractical for testing GUV technology due to limitations with shadowing, penetration, etc. As there is currently no universally adopted test method or FDA-recognized standard of conformance for UV disinfection performance, it is difficult to objectively assess efficacy across medical devices or set uniform acceptance criteria. This lack of standardization often leads to reliance on manufacturer-designed studies, which can vary in rigor and clinical relevance. Developing standardized test methods for UV-C disinfection is therefore a priority to ensure consistent and reliable assessment of microbicidal performance to support medical device reprocessing claims. The Panel will be asked to provide input on appropriate UV-specific performance testing to thoroughly evaluate germicidal UV as a reprocessing agent.

Hierarchy of resistance:

Another challenge is the lack of a well-defined hierarchy of microbial resistance to UV-C. While liquid chemical disinfectants have an established resistance hierarchy, with bacterial spores as the most resistant and lipid viruses among the most susceptible [1], the relative resistance rankings for UV-C are not fully characterized and may differ from the chemical disinfectants. For example, bacterial endospores are known to be highly UV-resistant [8], but organisms that are chemically resistant, such as mycobacteria, are not especially UV-resistant. Their tolerance to UV-C is similar to, or only slightly greater than, that of common vegetative bacteria and is much lower than that of spores [8]. Comprehensive comparative data for all pathogen types under UV exposure are limited, making it unclear which organisms best represent the "worst case" for UV efficacy testing. There is currently no consensus on the most UV-resistant microbe for standard validation, highlighting a knowledge gap. Panel input is requested to develop a scientifically justified, clinically relevant UV resistance hierarchy, which would help standardize test expectations and guide future research and the development of consensus standards.

Infection Prevention Intended Uses:

Healthcare associated infections (HAIs) are infections that patients acquire while, or soon after, receiving healthcare in a medical facility. They can be contracted in a number of ways, including through person-to-person transmission or contact with contaminated medical devices or environmental surfaces. HAIs represent significant and preventable sources of morbidity and mortality for patients. Treating and preventing HAIs is a major concern for medical facilities in terms of patient welfare and allocating healthcare resources for treatment and prevention. While reprocessing plays an important part in mitigating the risk for microbial contamination, it can be challenging to extrapolate the impact that reprocessing devices such as GUV, may have on HAIs. Microbiological performance of GUV medical devices has typically been demonstrated through *in vitro* microbiological testing, which generally is not sufficient to support HAI reduction or prevention intended uses. Currently, the Agency has not seen sufficient evidence

regarding the impact of automated UV microbial reduction devices on HAI acquisition. Typical reprocessing of environmental surfaces with chemical detergents is labor intensive and can be more error prone than automated processes. GUV microbial reduction systems also have drawbacks related to performance (e.g., impacts of shadowing, soiling and microbial resistance) and potential adverse effects (e.g., ozone, material degradation) of the technology.

Designing a clinical study to support the reduction of HAIs secondary to the implementation of UV air or medical surface microbial reduction would be difficult given the many variables that could concurrently affect clinical infection rates. Major variables may include:

- hospital size and level of care,
- seasonal and geographic variation in HAIs,
- 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.

Furthermore, healthcare infection control practices are informed and influenced by national guidelines and the practice of medicine. FDA does not regulate hospital infection control practices or HAI rates. FDA's role is to evaluate the safety and effectiveness of medical devices used for reprocessing practices such as disinfection. GUV devices for use in reduction of HAIs in a healthcare setting are not yet classified by FDA. An HAI reduction claim is typically recommended to be supported through clinical data demonstrating a reduction of HAI incidence in patients that can be directly attributed to the intended use of the subject medical device. 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. From FDA’s perspective, the role of automated UV microbial reduction devices requires further clinical evaluation to establish a clinical benefit. The Panel will be asked for recommendations regarding study designs that may assist FDA in evaluating HAI reduction or prevention intended uses.

Antimicrobial stewardship:

Antimicrobial stewardship refers to coordinated interventions designed to establish the appropriate use of antimicrobial agents by promoting the selection of optimal antimicrobial dose regimen when used in a clinical setting. The principles of antimicrobial stewardship extend to all antimicrobial technologies, including emerging GUV germicidal devices. It is important to incorporate stewardship while the Agency is developing our current thinking for this technology and monitor potential signs of microbial resistance development that could eventually limit the efficacy of GUV technology. Antimicrobial stewardship principles for GUV devices and their inclusion into established hospital cleaning and disinfection protocols should be thoroughly evaluated to guard against the potential development of antimicrobial resistance following prolonged exposure to GUV exposure. Therefore, an evaluation is recommended to prevent development of antimicrobial resistance when this technology is adopted. The Agency is aware of the following areas which may be considered as part of this evaluation:

- Appropriate Use and Clinical Selection
- Dose Optimization and Standardization
- Safety and Risk Management
- Integration with Infection Control Protocols

The Panel will be asked to provide input on these topics to help inform approaches to the evaluation of susceptibility testing, UV exposure limitations, and dose regimes to support antimicrobial stewardship for GUV devices.

Pandemic Preparedness

The COVID-19 PHE highlighted the critical need for additional disinfection technologies and emboldened the FDA to quickly modify existing regulatory approaches. In March 2020, the FDA created emergency policies that were time-limited, and in certain circumstances, allowed manufacturers to modify existing devices or introduce new UV devices and air purifiers to the market without undergoing the typical authorization process, while still ensuring these products met specific safety and performance expectations. This approach provided valuable real-world data about how these technologies perform in actual healthcare settings and revealed both their potential benefits and the importance of proper training and safety measures. In preparation for future public health emergencies, the FDA is seeking to leverage this experience and strengthen pandemic preparedness capabilities moving forward.

The FDA is seeking expert input from the Panel to address key questions, including how to standardize testing methods for UV technologies and establish clear guidelines for measuring their effectiveness against a wide spectrum of clinically relevant bacteria and viruses. Moving forward, the FDA aims to create regulatory approaches that can quickly adapt during health emergencies while maintaining safety standards for GUV devices.

Citations

1. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff
2. Rutala, W. A., and D. J. Weber. "Guideline for disinfection and sterilization in healthcare facilities, 2008. update: June 2024." Centers for Disease Control and Prevention (CDC) Atlanta, Georgia https://www. cdc. gov/infection-control/hcp/disinfection-and-sterilization/index. html (2024).
3. Browne, Katrina. "Brought to light: how ultraviolet disinfection can prevent the nosocomial transmission of COVID-19 and other infectious diseases." Applied Microbiology 1.3 (2021): 537-556.
4. Demeersseman, N., et al. "Shedding a light on ultraviolet-C technologies in the hospital environment." Journal of Hospital Infection 132 (2023): 85-92.
5. Salcedo, I., et al. "Photoreactivation and dark repair in UV-treated microorganisms: effect of temperature." Applied and Environmental Microbiology 73.5 (2007): 1594-1600.
6. Lamprecht-Grandío, María, et al. "Novel genes involved in resistance to both ultraviolet radiation and perchlorate from the metagenomes of hypersaline environments." Frontiers in microbiology 11 (2020): 453.
7. Suh D, Hockett Sherlock S, Dukes KC, Perencevich EN, Marra AR. Impact of UV-C on material degradation: a scoping literature review. Antimicrob Steward Healthc Epidemiol. 2025 Sep 2;5(1):e199. doi: 10.1017/ash.2025.10114. PMID: 40927244; PMCID: PMC12415791.
8. Coohill, Thomas P., and Jose-Luis Sagripanti. "Overview of the inactivation by 254 nm ultraviolet radiation of bacteria with particular relevance to biodefense." Photochemistry and photobiology 84.5 (2008): 1084-1090.
9. Malayeri, Adel Haji, et al. "Fluence (UV dose) required to achieve incremental log inactivation of bacteria, protozoa, viruses and algae." IUVA News 18.3 (2016): 4-6.9.

10. Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants, Issued Jan 3, 2000.
11. Spaulding E., 1968. Chemical disinfection of medical and surgical materials. In: Lawrence C. (Ed.), Block's Disinfection, Sterilization, and Preservation. Lea & Febiger, Philadelphia, pp.517-531.