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24 Hour Summary
General Hospital and Personal Use Devices Panel
Advisory Committee Meeting
December 10, 2025

Introduction:

A virtual meeting of the General Hospital and Personal Use Devices Panel of the Medical Device Advisory Committee was convened to discuss issues related to an emerging technology in the context of medical devices, germicidal ultraviolet (UV) light as a mode of disinfection. FDA is seeking to obtain feedback to improve the total product lifecycle evaluation of UV disinfection devices. This includes (but is not limited to) discussions around stakeholder perspective, performance testing, study design considerations, antimicrobial stewardship, regulatory considerations, and pandemic preparedness.

Device Description:

Note: this is not a device-specific Advisory Committee Meeting. This meeting focused on UV radiation-based microbial reduction and disinfection devices.

FDA presentations:

Opening remarks – RDML Raquel Peat, Ph.D., MPH

RDML Raquel Peat opened an FDA Advisory Committee Panel Meeting focused on germicidal UV medical devices, which are products that use electromagnetic energy to generate UV radiation that penetrates microorganism cell walls and destroys their ability to reproduce. The meeting was convened to fulfill requirements under the Food and Drug Omnibus Reform Act of 2022 related to pandemic preparedness devices, prompted by increased use of germicidal UV technology in healthcare environments since COVID-19 and the agency's receipt of Emergency Use Authorization requests for UV-based technologies during the pandemic. The agenda includes discussions on regulatory history, medical device reprocessing, microbicidal properties, current regulatory landscape, and challenges for germicidal UV devices, with the goal of improving healthcare preparedness and providing clear recommendations for manufacturers and healthcare workers.

Introduction/background - Katharine Segars, Ph.D.

This presentation outlined the purpose of the Advisory Committee meeting and provided an introduction to germicidal UV technology, including the definition of a medical device, regulatory background of germicidal UV devices, and the key topics for panel deliberation.

Overview of Medical Device Reprocessing – Yong Xue, Ph.D. and Elizabeth Bulger, MD

The first half of the presentation was provided by Dr. Xue. This presentation covered medical device reprocessing in general including the Spaulding classification used to identify the associated risk of a particular device, the requirements around the various level of disinfection, and associated performance requirements. The mechanism of action as well as challenges with germicidal UV were also discussed. The second half of the presentation covered how germicidal UV fits into clinical practice. This included both advantages and risks of germicidal UV.

Regulatory History of Germicidal UV Medical Devices – Stephen Anisko, M.S.

This presentation focused on the regulatory history of germicidal UV devices in the agency including Electronic Product Radiation Control requirements, consumer vs. medical devices, existing regulations, and an example of some special controls used to support these devices.

Current Challenges for Germicidal UV Medical Devices – Lianji Jin, Ph.D.

This presentation focused on existing areas of uncertainty around germicidal UV devices including innovation in this space, development of a hierarchy of resistance, claims around reduction/prevention of infection, antimicrobial stewardship, and pandemic preparedness.

Questions to the Panel- Dolly Singh, Ph.D.

Dr. Singh presented the specific questions the agency wanted the panel to deliberate on.

Stakeholder presentations:

Juan Gonzalez, Vice President of Engineering, Xenex

This presentation provided an over of the device Xenex manufactures including it being the first example of a whole room UV disinfector to get authorization from the agency as an adjunctive device. They discussed the testing needed to support their submission, suggestions on how to improve future reviews, and also provided challenges in the existing marketplace.

Sade Rolon, American Hospital Association/Association for the Health Care Environment

This presentation discussed the confusion present in the current market from the perspective of the healthcare facility/end users. It highlighted the confusion that exists around device intended uses, regulatory requirements, and the potential for misuse.

Jeff Veenhuis, President and CEO, Surfacide Manufacturing, Inc.

This presentation focused on the whole room UV disinfection device manufactured by Surfacide including performance requirements. They also discussed the challenges in the existing marketplace around misbranding and potential misuse of these devices.

FDA Questions/Panel Deliberations:

The following summarizes the recommendations received during panel deliberations:

Question 1a: Does the Panel have recommendations on performance testing specific for UV radiation reprocessing of medical devices that may support a standalone disinfection intended use?

Question 1b: 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 Recommendations:

Panel recommendations for 1a:

The panel received clarification from the FDA that germicidal UV intended for standalone disinfection refers to disinfection as the primary microbicidal process, as distinct from adjunctive, and is not meant to replace standard cleaning procedures. The panel commented on the variety in types and placement of devices and objects within the germicidal UV treatment space and the substantial challenges for achieving uniform UV coverage, as variations in room setup directly affect disinfection consistency. Direct line-of-sight requirements are critical for UV effectiveness, making shadowed areas critical points that require attention during validation protocols. A comprehensive validation strategy should incorporate before-and-after control sampling to quantify disinfection effectiveness using appropriate control samples. Strategic placement of dosimeters in worst-case locations can verify adequate UV dose delivery throughout the treatment area.

The validation process should focus on HAI pathogens that are commonly transmitted through surface contact in the intended use environment, as these represent the most clinically relevant targets for disinfection efficacy testing. Enclosed disinfection chambers offer the most controlled environment for validation, allowing for more predictable outcomes while requiring verification of device compatibility to ensure materials can withstand

germicidal UV exposure. These controlled settings present the greatest potential for standalone disinfection claims when proper validation demonstrates effectiveness. In contrast, whole-room disinfection presents significant challenges due to variability in room configurations and the lack of steady-state conditions (i.e. devices being moved around based on procedures) in hospital settings. Validation endpoints can include quantifiable microbial log reduction in target organisms, HAI reduction in real-world settings, and comparative effectiveness analysis relative to established traditional disinfection methods.

The development of standalone disinfection capabilities requires establishing objective standards, similar to those used for chemical disinfection, with validation demonstrating that germicidal UV treatment can achieve appropriate disinfection levels independent of traditional cleaning protocols.

Panel recommendations for 1b:

A pragmatic study design should be used and account for the inherent complexity of human factors' challenges in healthcare settings, where robotic systems may be involved, and practical cleaning procedures could be compromised. This included shadowing effects, where certain areas will not receive full germicidal UV doses and presents a significant challenge that users may not fully recognize. The study design should incorporate these practical elements and evaluate how germicidal UV disinfection systems function within actual clinical environments. Using each healthcare setting as its own control may account for variability across different facilities, though this approach requires careful planning and consideration of site-specific factors.

Sample size calculations should account for sufficient specimens to detect meaningful effects of UVC treatment, considering the multiple variables at play, including hand hygiene practices, device-specific procedures, and hospital-specific protocols. These studies will likely need to be large-scale due to the numerous confounding factors that influence infection transmission in healthcare settings. Critical questions can arise regarding the appropriateness of sampling methods for assessing bioburden reduction. The methodology can include log recovery measurements before and after treatment using inoculated coupons strategically placed throughout the treatment area, with careful comparison between control and irradiated samples. This approach can provide quantifiable data on the actual reduction achieved by germicidal UV treatment under real-world conditions.

A current challenge the FDA faces is developing strategies to differentiate among the numerous germicidal UV disinfection products currently available, as most devices make similar bioburden reduction claims despite potentially different performance characteristics. Large-scale studies focusing, stepwise, on both bioburden reduction and subsequently HAI rates will likely be necessary. The study approach may distinguish between airborne and surface-transmitted pathogens, as each presents unique challenges for UV disinfection validation. Surface contamination proves particularly challenging due to contributions from prior room occupants, healthcare worker practices, and environmental factors such as sink drains, which represent known infection hotspots. The selection of clinically relevant multidrug-resistant organisms, including or Methicillin-Resistant *Staphylococcus aureus*, and carbapenem-resistant pathogens, may guide study design to ensure clinical relevance.

While FDA's regulatory purview focuses on device safety and effectiveness rather than financial considerations, collaboration with the Centers for Medicare & Medicaid Services

may provide additional incentives for adoption of validated UV disinfection technologies. The ongoing workforce challenges in hospitals can affect device utilization. Well-designed, pragmatic studies that demonstrate clinical relevance through appropriate intended-use settings, bioburden reduction, and inoculation coupon methodologies can be useful as a starting place prior to infection reduction or prevention studies, in establishing the regulatory framework for these emerging technologies.

Question 2: Does the Panel have recommendations on what information would be needed to support a general hierarchy of resistance for UV?

Panel Recommendations:

The development of effective UV disinfection validation should utilize baseline pathogens that do not exhibit secondary effects, where it becomes challenging to trace the source of inoculation. This approach provides a clear starting point for creating a hierarchical understanding of pathogen susceptibility to germicidal UV treatment. Rooms and devices could be better designed to optimize germicidal UV reception and distribution, but this requires a fundamental understanding of the biology of target organisms and spores. Identifying the best candidate organisms for testing, such as pigmented spores that demonstrate known germicidal UV resistance characteristics, allows for more predictable and reproducible validation outcomes.

The establishment of standardized protocols through round-robin testing across various laboratories can be used for creating accepted testing methods. The FDA may also reach out to the Office of Science and Engineering Laboratories. These standardized approaches should account for differences between gram-positive and gram-negative organisms, as their structural differences significantly impact germicidal UV susceptibility. Having clearly defined endpoints would facilitate consistent evaluation across different regulatory submissions.

Understanding pathogen susceptibility profiles can guide the development of targeted disinfection strategies, but this requires careful separation of HAI organisms from environmental pathogens that may not pose the same clinical risks. Dividing organisms into distinct categories based on their clinical relevance, environmental persistence, and germicidal UV susceptibility characteristics allows for more focused validation efforts that address the most pressing healthcare concerns while maintaining scientific rigor in the evaluation process.

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 Recommendations:

UV disinfection devices should incorporate safety measures to account for instances when the device has not been used correctly or has failed to achieve intended effectiveness levels. The implementation of audible and visual alarms that activate when devices have not reached their target effectiveness provides users with immediate feedback about treatment adequacy. The assessment of such functionality should occur through established monitoring processes, recognizing that treatment failures may result from insufficient dosing or inadequate monitoring of lamp life rather than inherent device design flaws. The variability in current device capabilities suggests that functionality requirements should be carefully evaluated on a case-by-case basis. Additionally, appropriate monitoring of lamp lifespan ensures that devices maintain their disinfection capability throughout their operational life, as lamp degradation directly impacts germicidal UV output and treatment effectiveness.

When developing regulatory guidance, careful consideration must be given to lessons learned from other disinfection technologies, particularly quaternary ammonium compounds and their tendency to select for drug resistance through tolerance development. The contamination of these chemical products by gram-negative organisms serves as a cautionary example of how disinfection methods can inadvertently contribute to resistance issues. This historical context can be used to inform the FDA of how germicidal UV disinfection guidance addresses potential unintended consequences.

Question 4: 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 Recommendations:

The distinction between reducing pathogen loads in the environment and preventing HAIs represents a critical regulatory consideration that requires clear categorization and communication. The FDA can proactively include the inherent limitations of UV disinfection technologies, including issues with shadowing effects and low penetration in complex environments in publicly available information. Clear communication from the FDA regarding these technological limitations will help healthcare facilities make informed decisions about implementation.

Establishing consensus with the Environmental Protection Agency (EPA) for defining clear jurisdictional boundaries between what constitutes a medical device under FDA oversight versus environmental disinfection applications that fall under EPA purview would be helpful. This coordination will prevent regulatory confusion and ensure that manufacturers understand which agency has authority over their specific germicidal UV disinfection applications. Clear delineation of FDA versus EPA responsibilities will streamline the regulatory process and provide consistent oversight across different use cases.

The FDA should include comprehensive summaries and labeling with testing protocols and results, particularly focusing on how consistent dose delivery was ensured and validated during testing in publicly available information. This information may include published studies and internal testing data that sponsors may not have made publicly available.

Proactive and objective statements regarding testing methodologies, device limitations, and demonstrated benefits will provide stakeholders with the information necessary to understand what these devices can and cannot accomplish in real-world healthcare settings. This transparency in testing documentation will support evidence-based decision-making.

Question 5: What other considerations for innovations in germicidal UV reprocessing of medical devices does the Panel recommend?

Panel Recommendations:

The development of effective process measures for germicidal UV disinfection validation can incorporate fluorescent markers for room cleaning verification and ATP testing for general cleanliness evaluation. These indicators can provide rapid feedback on whether devices have been successfully reprocessed in an efficient manner, offering healthcare facilities immediate confirmation of treatment completion. However, while these process measures offer convenience and speed, they should complement rather than replace more definitive validation methods and limitations were noted with respect to differentiation of live or dead microorganisms. The ability to achieve rapid turnaround times, ideally within 30 minutes, for determining whether target organisms have been effectively inactivated would significantly enhance the practical utility of UV disinfection systems in healthcare settings. This rapid feedback capability could allow for immediate corrective action if treatment proves inadequate.

Validation protocols maybe be based on culture methods that provide quantitative data on viable organism counts, as understanding the number of live organisms present before and after treatment represents a more reliable method of disinfection assessment. Ultimately, regulatory approaches should remain open to innovative validation methods that can provide reliable, rapid assessment of disinfection effectiveness while maintaining scientific rigor. The balance between speed, accuracy, and practical implementation will be crucial for developing validation standards that support both patient safety and operational efficiency in healthcare environments.

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Transcripts:

Transcripts may be downloaded from the link below when they become available:
UPDATED MEETING TIME AND PUBLIC PARTICIPATION INFORMATION: December 10, 2025: General Hospital and Personal Use Devices Panel Meeting Announcement - 12/10/2025 | FDA
OR

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