Food and Drug Administration
Center for Devices and Radiological Health

Summary Minutes of the General Hospital and Personal Use Devices Advisory Committee Meeting
December 10, 2025

Location: The meeting was held virtually via videoconference through Zoom platform. The meeting presentations were heard, viewed, captioned, and recorded through an online video conferencing platform.

Topic: The Committee discussed and made recommendations on 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 (TPLC) 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.

These summary minutes for the December 10, 2025, meeting of the General Hospital and Personal Use Devices Advisory Committee of the Food and Drug Administration were approved on 1/26/2026.

I certify that I attended the December 10, 2025, meeting of the General Hospital and Personal Use Devices Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

Evella F. Washington
Designated Federal Officer, GHPUDP

William R. Jarvis, M.D.
Chairperson, GHPUDP

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The following is the final report of the General Hospital and Personal Use Devices Advisory Committee meeting held on December 10, 2025. This link can be used to view all written and presented materials considered by the committee and a verbatim transcript that will be available in approximately six weeks:

https://www.fda.gov/advisory-committees/advisory-committee-calendar/updated-meeting-time-and-public-participation-information-december-10-2025-general-hospital-and

All external requests for the meeting transcript should be submitted to the Center for Devices and Radiological Health (CDRH) Freedom of Information Office.

Issue: The General Hospital and Personal Use Devices Panel Advisory Committee Meeting of the Food and Drug Administration, Center for Devices and Radiological Health, virtually met on December 10, 2025, through videoconference. Prior to the meeting, the members and temporary voting members were provided with the briefing materials from the FDA and the stakeholders. The meeting was called to order by William Jarvis, M.D. (Chairperson). The conflict of interest statement was read into the record by Evella Washington (Designated Federal Officer). There were approximately 24 people in attendance. There were 2 Open Public Hearing (OPH) speaker presentations.

Attendance:

Voting Chair: William R. Jarvis, M.D.

Voting Member: Aamir Siddiqui, M.D.

Temporary Non-Voting Members: Charity Morgan, Ph.D.; Matthew J Arduino, MS, DrPH, FSHEA, M(ASCP); C. Cameron Miller, Ph.D.

Industry Representative: Nancy K. Sauer, RAC

Consumer Representative: Rachel Brummert

Patient Representative: Debra L. Dunn

Acting Office Director CDRH/OPEQ/OHTIV: RDML Raquel Peat, Ph.D., MPH

Division Director CDRH/OPEQ/OHTIV/DHT4C: Christopher Dugard, MS

Designated Federal Officer: Evella F. Washington

FDA speakers: Katharine Segars, Ph.D.; Yong Xue, Ph.D.; Elizabeth Bulger, MD; Stephen Anisko, M.S.; Lianji Jin, Ph.D.; Dolly Singh, Ph.D.

FDA members: Sreekanth Gutala, Ph.D.

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Stakeholders' presenters: Juan Gonzalez and Sarah Simmons; Sade Rolon; Jeffry Veenhuis

Open Public Hearing Speakers: David J Brenner, PhD, DSc; Gary Kellstrom, Jr.

The agenda was as follows:

9:00 a.m.	**Call to Order and Opening Remarks** **Panel Introductions**	**William Jarvis, M.D.** Panel Chair
9:05 a.m.	**Conflict of Interest Statement**	**Evella Washington** Designated Federal Officer
9:10 a.m.	**Opening Remarks**	**RDML Raquel Peat, Ph.D., MPH** Acting Office Director CDRH/OPEQ/OHTIV
9:15 a.m.	**Introduction and Background**	**Katharine Segars, Ph.D.** Assistant Director CDRH/OPEQ/OHTIV
9:25 a.m.	**Overview of Medical Device Reprocessing**	**Yong Xue, Ph.D.** CDRH/OPEQ/OHTIV **Elizabeth Bulger, MD** CDRH/OPEQ/OHTIV
9:40 a.m.	**Regulatory History of Germicidal UV Medical Devices**	**Stephen Anisko, M.S.** Acting Assistant Director CDRH/OPEQ/OHTIV
9:50 a.m.	**Current Challenges for Germicidal UV (GUV) Medical Devices**	**Lianji Jin, Ph.D.** CDRH/OPEQ/OHTIV
10:00 a.m.	**Clarifying Questions from the Panel**	
10:20 a.m.	**Break**	
10:30 a.m.	**Stakeholder Presentations**	**Juan Gonzalez** Vice President of Engineering Xenex **Sade Rolon** American Hospital Association/ Association for the Health Care Environment

		Jeff Veenhuis President & CEO Surfacide Manufacturing, Inc.
11:15 a.m.	**Clarifying Questions from the Panel**	
11:30 a.m.	**Open Public Hearing***	**William Jarvis, M.D.** Panel Chair
12:30 p.m.	**Clarifying questions from Panel**	
12:40 p.m.	*Lunch*	
1:40 p.m.	**FDA Questions to the Panel**	**Dolly Singh, Ph.D.** CDRH/OPEQ/OHTIV
1:45 p.m.	**Panel Deliberations**	**William Jarvis, M.D.** Panel Chair
3:30 p.m.	**Adjourn**	**William Jarvis, M.D.** Panel Chair

Questions to the Committee:

1. **DISCUSSION:** 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.

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?

1b: In addition, manufacturers may also be interested in reducing or preventing Healthcare-

Associated Infections, known as HAI, 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?

Committee Discussion: *The Committee emphasized that recommendations for UV performance testing must account for the wide variability in device types and use contexts, distinguishing clearly between enclosed chambers, in-room surface devices, and air-based systems. Members agreed that standalone disinfection does not eliminate the need for cleaning but would require robust, standardized performance testing demonstrating equivalence to established chemical disinfection at the appropriate Spaulding classification level. Enclosed chamber devices were viewed as the most feasible candidates for standalone indications, whereas whole room systems raised substantial concerns related to geometry, shadowing, dose variability, and real-world use conditions. The Committee stressed the need for worst-case positioning, dosimetry, representative organisms, and validated in-use testing methods, noting the lack of current consensus standards.*
With respect to HAI reduction claims, the Committee agreed that while laboratory and in-use bioburden reduction studies are achievable, demonstrating a causal reduction in HAIs is extremely challenging due to variability in infection control practices, human factors, and transmission pathways. Members recommended pragmatic study designs, such as step-wise or pre/post observational studies using each site as its own control, rather than relying solely on large, randomized trials, which were viewed as costly, impractical, and unlikely to be repeated. The Committee emphasized focusing on HAI-relevant organisms, appropriate sampling methods, and clinically meaningful endpoints, while acknowledging that post-market and real-world evidence may play a complementary role but cannot replace premarket evidence of safety and effectiveness.

2. **DISCUSSION:** 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?

Committee Discussion: *The Committee agreed that a general UV resistance hierarchy is not currently supported by the literature due to highly variable study methods. Members emphasized the need for a standardized, consensus testing protocol, ideally developed through round-robin, multi-laboratory studies, to ensure reproducibility. They recommended basing the hierarchy on fundamental microbiology, using a small number of resistance categories with representative organisms relevant to healthcare rather than device-specific testing. The Committee stressed that susceptibility should be defined using quantified UV dose/fluence*

(mJ/cm²) under controlled conditions, while application-specific factors such as soiling, angle of incidence, and shadowing should be addressed separately. Overall, the panel agreed that a shared hierarchy is feasible only with standardized methods and once established, should not be redeveloped independently by each manufacturer.

3. **DISCUSSION:** 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?

Committee Discussion: *The Committee noted that concerns raised in the question relate to potential UV tolerance rather than antimicrobial (antibiotic) resistance, emphasizing that UV devices are not known to induce antibiotic resistance. Members agreed that evidence for clinically meaningful UV resistance is limited and that the issue remains largely theoretical. The primary concern identified was sublethal UV exposure resulting from insufficient dose delivery, improper use, or degraded lamp performance, which could allow organisms to survive and potentially develop tolerance. Several members highlighted that device functionality safeguards, such as dose monitoring, lamp life tracking, and audible or visual alarms indicating inadequate exposure, could support appropriate use and stewardship. The Committee cautioned against placing responsibility for long-term resistance surveillance solely on device manufacturers and suggested that, if UV tolerance becomes a concern, it would be better addressed through ongoing monitoring and standardized susceptibility benchmarks, similar to approaches used in water treatment, rather than through prescriptive regulatory requirements. Overall, the Committee viewed UV stewardship as primarily a matter of ensuring adequate dose delivery and proper integration with existing infection control practices, rather than a demonstrated resistance risk requiring new regulatory controls.*

4. **DISCUSSION:** During the COVID-19 public health emergency, certain emergency use authorizations utilized UV as the primary microbiologic agent, such as UV decontamination systems used to reprocess personal protective equipment. 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?

Committee Discussion: *The Committee emphasized that increasing innovation in UV technologies has created confusion among healthcare providers regarding authorized intended uses and limitations. Members recommended clearly categorizing UV devices (e.g., enclosed chambers for device reprocessing, environmental microbial reduction systems, and*

technologies intended to reduce HAIs) and explicitly distinguishing among these uses so that claims in one category are not assumed to apply to others. The Committee stressed the importance of clear, FDA-led communication to healthcare providers describing what UV devices can and cannot do, including known limitations such as low penetration, shadowing, and the requirement for thorough pre-cleaning. Concerns were raised about misleading or overstated marketing, particularly in rapidly evolving areas. Members also highlighted the need for coordination and alignment between FDA and EPA, clarifying regulatory authority for devices used in healthcare settings versus non-healthcare environments. Finally, the Committee supported requiring transparent summaries of device testing, including how and under what conditions devices were evaluated, especially when data are unpublished, to allow clinicians to better understand performance claims and make informed decisions.

5. **DISCUSSION:** What other considerations for innovations in germicidal UV reprocessing of medical devices do the Panel recommend?

Committee Discussion: *The Committee recommended that future innovations in germicidal UV reprocessing incorporate reliable process measures that allow users to confirm that devices have been reprocessed as intended and that the UV system delivered the required performance. Members emphasized the need for rapid, practical indicators of successful reprocessing, beyond current approaches such as fluorescent markers or ATP testing. The Committee cautioned that validation of UV efficacy should be grounded in culture-based methods, as these directly assess viable organisms, and warned against relying solely on PCR or ATP results as evidence of effectiveness. At the same time, some members noted that rapid molecular methods could have a potential role if properly correlated with culture-based outcomes, particularly as a research tool to provide faster feedback on pathogen inactivation. Overall, the discussion highlighted the importance of developing robust, biologically meaningful verification methods to support safe and effective implementation of UV reprocessing technologies.*

The meeting was adjourned at approximately 3:00 p.m.