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Discussion Questions

General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee

UV Germicidal Devices

December 10, 2025

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?

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.

a. 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.

a. 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?