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Association for the Health Care Environment

Ultraviolet Device Use in the Health Care Environment

Presentation for FDA General Hospital & Personal Use Advisory Committee meeting – December 10, 2025

American Hospital Association™

Advancing Health in America

Introduction

Sade Rolon

MBA, CHESP, CMIP, T-CHEST, T-CSCT

AHE Advisory Board Member

Lizzie Ortolano

Executive Director
Association for the Health Care Environment (AHE)

Association for the Health Care Environment

Safety is our Priority

- Actionable insights to ensure safe care environments
- From information to practical application
- Use case scenarios

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Association for the Health Care Environment (AHE)

- One of six Professional Membership Groups of the American Hospital Association (AHA)
- Representing over 2500 professionals responsible for establishing and maintaining health care environments that are free of surface contamination and that support safety, service, and efficient and effective operation
- Our members are key partners with other departments within a hospital (facility management, infection prevention, supply chain, and risk management)
- AHE is committed to elevating health care environmental services through education, advocacy and collaboration

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Context and Situation

- There is a need to address market confusion surrounding UV disinfection and device regulation in multiple sectors
- Our members have revealed misconceptions about FDA guidelines and regulatory pathways
- Seeking clarity and education for vendors, our members, and health care organizations

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Background

- UV technology has evolved significantly since the pandemic
- Statements by vendors/organizations do not necessarily align with FDA's definition and guidance
- Vendors/consumers are not operationalizing devices as intended – significant impacts to health and safety
- Concerns about mis-branded devices

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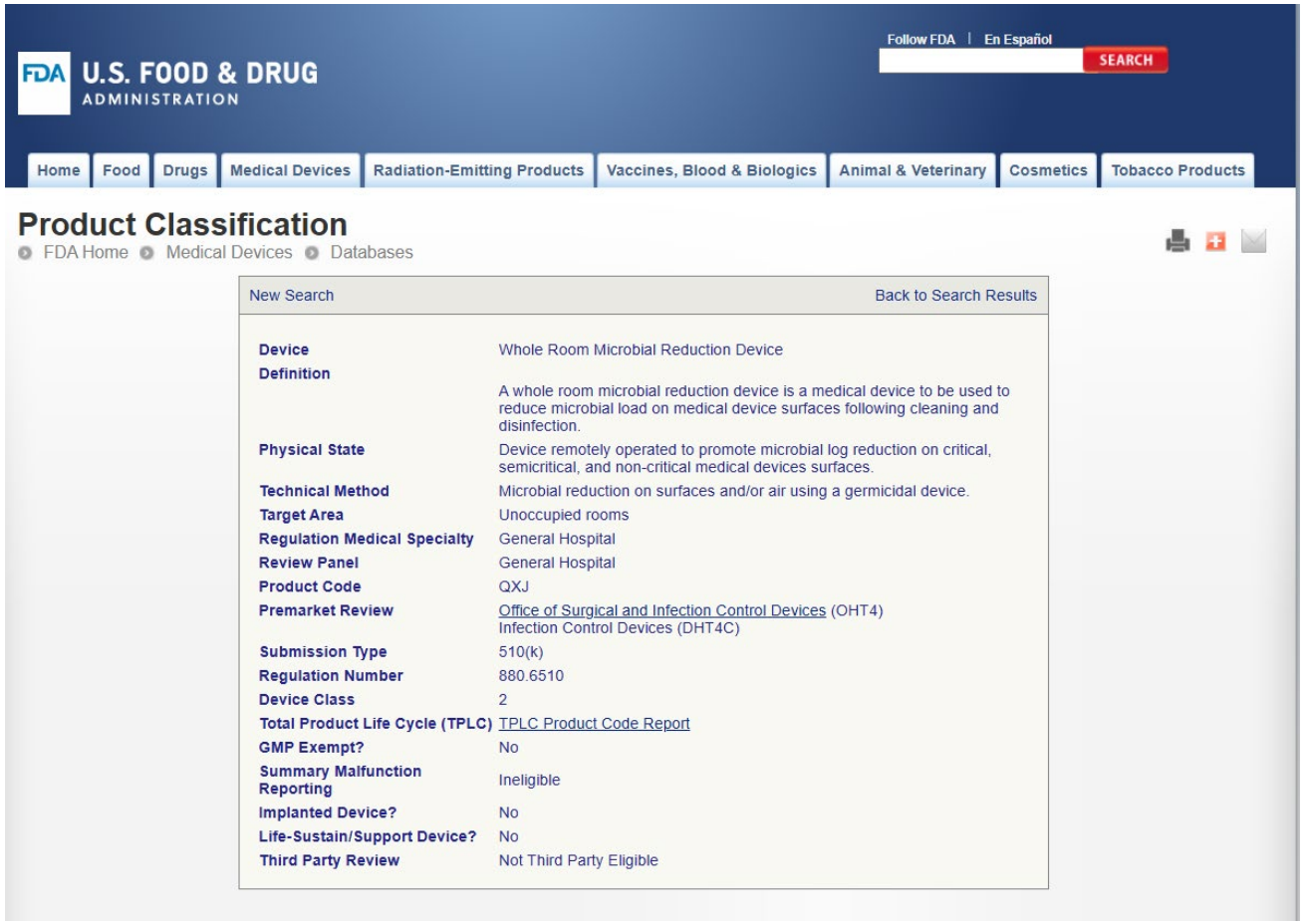
FDA Product Classification

- FDA regulates UV devices intended to reduce microbial load
- FDA has regulated “Whole Room Microbial Reduction Device”
- Intended use-case versus actual use case in health care



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Product Classification

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Device	Whole Room Microbial Reduction Device
Definition	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.
Physical State	Device remotely operated to promote microbial log reduction on critical, semicritical, and non-critical medical devices surfaces.
Technical Method	Microbial reduction on surfaces and/or air using a germicidal device.
Target Area	Unoccupied rooms
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	QXJ
Premarket Review	Office of Surgical and Infection Control Devices (OHT4) Infection Control Devices (DHT4C)
Submission Type	510(k)
Regulation Number	880.6510
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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Questions For Clarity in the Sector

- What is the intended use for these devices if it to be used in a health care environment?
- If a device does fall under the category and needs to be regulated, what are the steps to ensure the device can be safely used in a health care environment?
- Will older generations be allotted a grace period or be allotted a time period to be "grandfathered" should regulations be enforced?
- If something is mis-branded how is that currently regulated?

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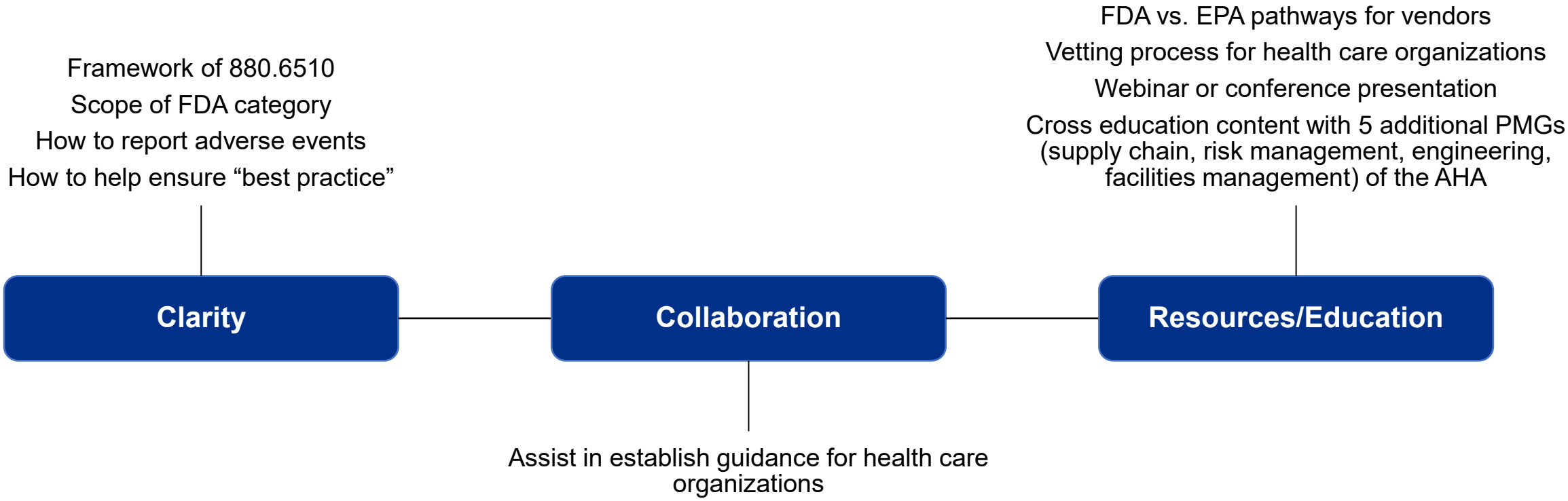
Suggested Recommendations



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Thank you for your time!

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