FDA is committed to ensuring digital accessibility for people with disabilities. We are continually improving the user experience for everyone and applying the relevant accessibility standards. At the time of initial posting on **December 16, 2025**, the attached **presentation** may not be fully accessible to users using assistive technology. A fully accessible version of the **presentation** is in preparation and will be posted as soon as it is ready. We regret any inconvenience that this may cause our readers.

Please let us know if you encounter accessibility barriers by contacting **Evella Washington at:** **Evella.Washington@fda.hhs.gov**

XENEX®
Germ-Zapping Solutions™

LightStrike+

Xenex Disinfection Services Inc.

Dr. Sarah Simmons, Sr. Science Director
Juan L. Gonzalez, VP of Eng. & QARA

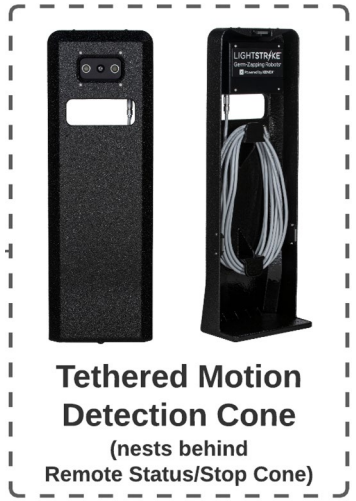
December 10, 2025

Agenda

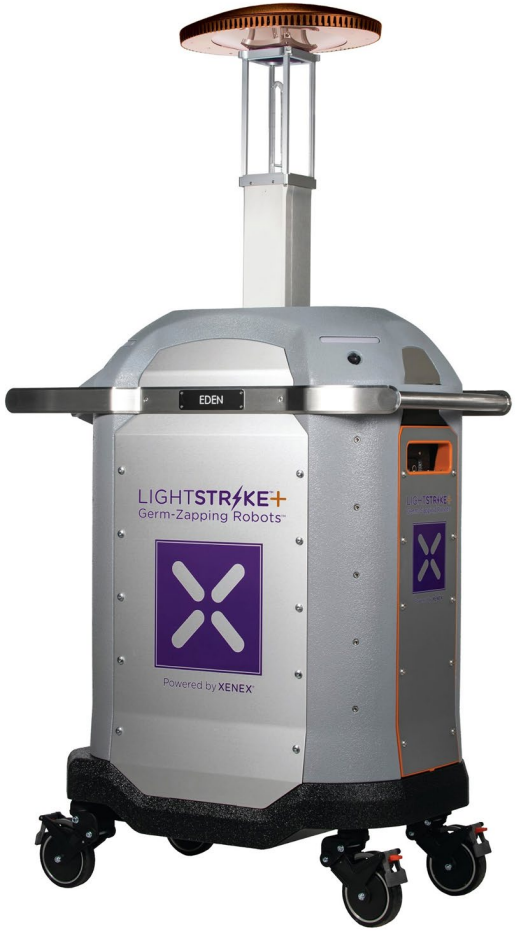
1. LightStrike+ Device Description
2. Intended Use / Indications for Use
3. Slide 3
4. Slide 4
5. Slide 5
6. The Future Goal

LightStrike+ Device Description

- Xenon gas flash lamp produces pulsed broad-spectrum germicidal UV light
- High intensity, pulsed, broad spectrum UV light deactivates spores, and bacteria
- Two models: 67Hz and 1.5Hz pulse rates
- Room to be treated selected via User Interface
- Physical push button used to start cycle
- Wireless communications used to track compliance with protocols
- Tethered Motion Detection Cone protects point of ingress
- Remote Status/Stop Cone displays cycle status and allows for termination of cycle from outside the room



Tethered Motion Detection Cone
(nests behind Remote Status/Stop Cone)



Remote Status/Stop Cone

Intended Use / Indications for Use

The Xenex LightStrike™+ is a pulsed, broad-spectrum, high-intensity, germicidal UV light system intended to perform ***microbial reduction*** *on non-porous, non-critical medical device surfaces, free from visual soiling, after manual cleaning and disinfection practices. LightStrike+ is intended for use in* ***unoccupied*** *operating rooms, hospital rooms, and other clinical settings* ***where non-critical medical devices are present*** *as an* ***adjunct to existing manual cleaning and disinfection practices****. The system is for over-the-counter (OTC) use.*

Micro Testing Volume

Microbiological bench testing requirements were unduly burdensome

- 18 total organisms tested
- Testing against non-hospital pathogens is not needed and confusing for customers
- Testing against extremely resistant organisms like D. radiodurans is not indicative of real-world product performance

Labeling Requirements

Cycle time information for devices should include all components of the treatment process

- Some lamp designs require significant warm up before reaching adequate UV emissions
- Some lamp designs may need cool down times before the device can be transported safely
- Larger spaces will require more than one treatment position, clear guidance should be given to users

Usability Requirements

UV devices have unique usability considerations that should be included in evaluations

- UV is line of sight technology, and multiple positions should be required in rooms where not all high-touch surfaces have direct exposure. Reliance on reflected light to reach these surfaces is inadequate
- Mobile UV devices require transport across healthcare facilities. The design of these systems can make transport ergonomically difficult or dangerous
- Lamps for UV devices become hot during use. Design requirements to address thermal hazards should be considered

The Future Goal

In close collaboration with FDA, Xenex lead the efforts to establish the QXJ product category (Whole Room Microbial Reduction).
However…

- Uptake has been minimal
- Regulatory messaging has been confused
- Only one other company has received clearance

What are we hearing from the market?

- “Additional disinfection is not a priority.”
- “Show me how this saves me money.”
- “I can buy UV robots without Medical Device authorization.”

What is needed to maximize the benefit to public health?

- Reimbursement Code
- Standard of Care
- Clear regulatory messaging
- An HAI Reduction Claim

XENEX®
Germ-Zapping Solutions™

Thank You!