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

surfacide®
UV Technology

Manufacturer Perspective

Jeffry D. Veenhuis
President & CEO
Surfacide Manufacturing, Inc.

DECEMBER 2025

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INTRODUCTION & BACKGROUND:

- 30+ years in medical device experience
- Neurosurgery/ENT/ Orthopedics
- Medtronic: Spinal & Neuro Distribution
- Insight: Intraoperative Neuromonitoring
- Surfacide Manufacturing Inc.
  - Surface disinfection
  - UV-C FDA Pre-Sub in 2017
  - DeNovo pathway
  - 510(k) pathway


02
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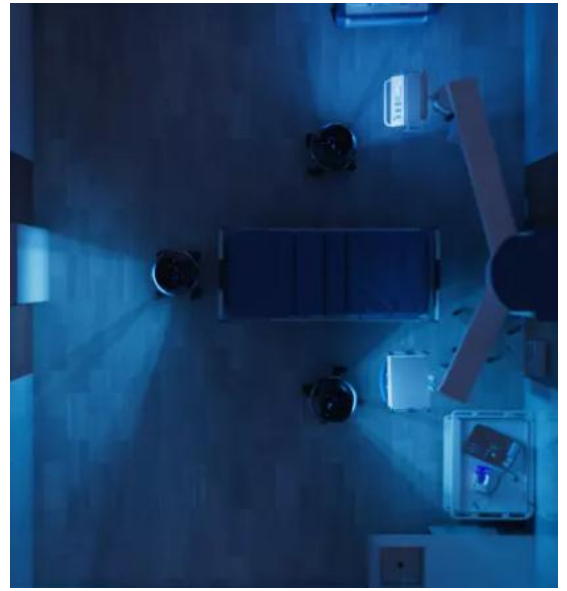
Procedure Rooms (OR, Cath Lab, L&D, Endo Suite)

Patient Rooms

Patient Bathrooms

Intensive Care Units



Helios+ is adaptable, with validated, customizable configurations.

surfacide®

FRA

§ 880.6500 Medical ultraviolet air purifier.

(a) Identification. A medical ultraviolet air purifier is a device intended for medical purposes that is used to destroy bacteria in the air by exposure to ultraviolet radiation.

(b) Classification. Class II (performance standards).

KMG

§ 880.6710 Medical ultraviolet water purifier.

(a) Identification. A medical ultraviolet water purifier is a device intended for medical purposes that is used to destroy bacteria in water by exposure to ultraviolet radiation.

(b) Classification. Class II (performance standards).

MKB

§ 880.6500 Medical ultraviolet air purifier.

(a) Identification. A medical ultraviolet air purifier is a device intended for medical purposes that is used to destroy bacteria in the air by exposure to ultraviolet radiation.

(b) Classification. Class II (performance standards).

OSZ

§ 880.6600 Ultraviolet (UV) radiation chamber disinfection device.

(a) Identification. An ultraviolet (UV) radiation chamber disinfection device is intended for the low-level surface disinfection of non-porous equipment surfaces by dose-controlled UV irradiation. This classification does not include self-contained open chamber UV radiation disinfection devices intended for whole room disinfection in a health care environment.

(b) Classification. Class II (special controls).

SCS

§ 880.6511 Ultraviolet Radiation Disinfection Chamber Device.

(a) Identification. An ultraviolet radiation disinfection chamber device is intended to disinfect patient contacting medical devices using UV radiation after the device has been cleaned. Disinfection of the medical device is achieved within an enclosed chamber through the exposure to UV radiation.

(b) Classification. Class II (special controls).

QXJ

§ 880.6510 Whole Room Microbial Reduction Device.

(a) Identification. 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.

(b) Classification. Class II (special controls).

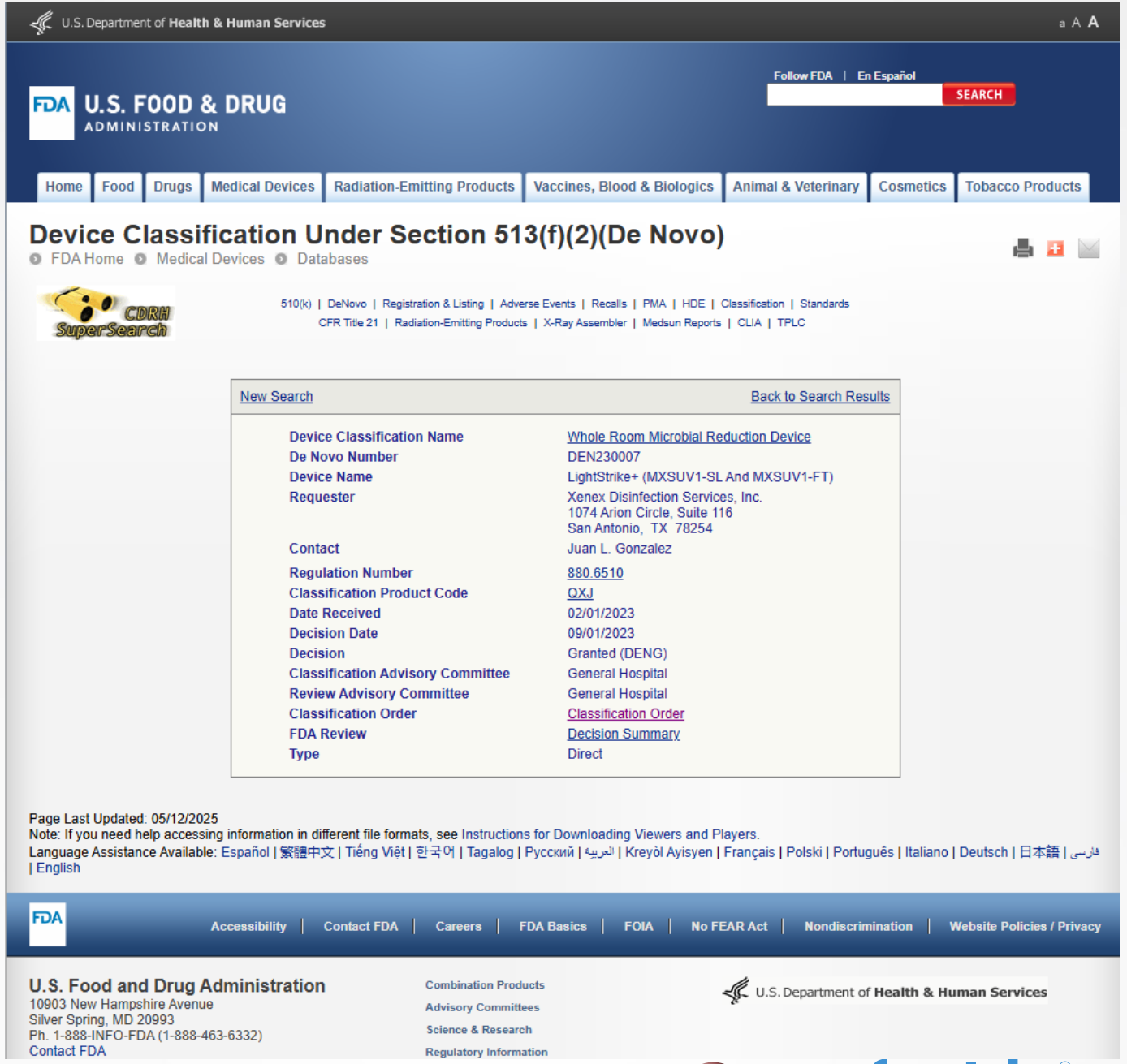
WHOLE ROOM MICROBIAL REDUCTION DEVICE

Classification Product Code: QXJ

FDA identifies this generic type of device as:

Whole room microbial reduction device.

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.



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Device Classification Under Section 513(f)(2)(De Novo)

FDA Home › Medical Devices › Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search — Back to Search Results

Device Classification Name	Whole Room Microbial Reduction Device
De Novo Number	DEN230007
Device Name	LightStrike+ (MXSUV1-SL And MXSUV1-FT)
Requester	Xenex Disinfection Services, Inc. 1074 Arion Circle, Suite 116 San Antonio, TX 78254
Contact	Juan L. Gonzalez
Regulation Number	880.6510
Classification Product Code	QXJ
Date Received	02/01/2023
Decision Date	09/01/2023
Decision	Granted (DENG)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General Hospital
Classification Order	Classification Order
FDA Review	Decision Summary
Type	Direct

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
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U.S. Department of Health & Human Services

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510(k) Premarket Notification

FDA Home › Medical Devices › Databases

New Search Back To Search Results

Device Classification Name	Whole Room Microbial Reduction Device
510(k) Number	K242604
Device Name	Helios+ UV-C System
Applicant	PreventaMed Technologies, Inc. Dba Surfacide Manufacturing W226N918 Northmound Drive, Suite 300 Waukesha, WI 53186
Applicant Contact	Jeffry Veenhuis
Correspondent	PreventaMed Technologies, Inc. Dba Surfacide Manufacturing W226N918 Northmound Drive, Suite 300 Waukesha, WI 53186
Correspondent Contact	Jeffry Veenhuis
Classification Product Code	QXJ
Date Received	08/30/2024
Decision Date	05/27/2025
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed by Third Party	No
Combination Product	No
Predetermined Change Control Plan Authorized	No

Page Last Updated: 10/20/2025

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QXJ: Whole Room Microbial Reduction Device:

U.S. Department of Health & Human Services

a A A

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TPLC - Total Product Life Cycle

FDA Home ▸ medical devices ▸ databases

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510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search | show TPLC since 2020 | Back to Search Results

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.
Product Code QXJ
Regulation Number 880.6510
Device Class 2

Premarket Reviews

Manufacturer	Decision	
PREVENTAMED TECHNOLOGIES, INC. DBA SURFACIDE MANUFACTURING		
	SUBSTANTIALLY EQUIVALENT	1
XENEX DISINFECTION SERVICES, INC.		
	GRANTED	1

Recalls

	Manufacturer	Recall Class	Date Posted
1	XENEX Disinfection Services Inc.	II	Apr-23-2024

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surfacide

QXJ: Special Controls: DEN230007-S001.Letter.DENG.pdf

FDA believes that ***Class II (special) controls*** provide reasonable assurance of the ***safety and effectiveness of the device type***. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	Mitigation Measures
Exposure to microbiocidal agent, leading to skin and eye damage	Non-clinical performance testing Biocompatibility evaluation Software verification, validation, and hazard analysis Labeling
Respiratory mucous membrane irritation and pulmonary edema due to chemical exposure	Non-clinical performance testing Biocompatibility evaluation
Patient cross-contamination due to device failure leading to inadequate microbial reduction	Non-clinical performance testing Labeling Software verification, validation, and hazard analysis
Electrical shock	Electrical safety testing Non-clinical performance testing Labeling
Interference with other devices	Electromagnetic compatibility testing Electrical safety testing Wireless coexistence testing Labeling

QXJ: Special Controls: DEN230007-S001.Letter.DENG.pdf

Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) ***Performance testing must demonstrate microbial log reduction*** of the demonstrated most resistant microorganism on medical device surfaces commensurate with the intended level of microbial reduction;

(ii) ***Simulated use testing must evaluate device performance*** under simulated worst-case use conditions (e.g., soiling, room objects and surfaces, distances);

(iii) ***In-use testing must evaluate device performance*** under real-world use conditions;

(iv) Performance testing must demonstrate the ***photobiological safety*** of any lamps or lamp systems;

(v) Performance testing must evaluate ***safety features intended to prevent exposure and ensure that device operation can only occur in an unoccupied environment***; and

(vi) Performance testing must characterize the ***long-term material compatibility*** of the microbiocidal agent on clinically relevant surfaces and/or devices.

Biocompatibility testing must demonstrate safe residual levels of chemicals on medical devices surfaces and/or gaseous byproducts in air. Software verification, validation, and hazard analysis must be performed for any software components.

Performance data must demonstrate the ***electromagnetic compatibility (EMC) and electrical safety*** of the device.

Labeling must include:

(i) ***Warnings and instructions*** to ensure the device is operated in an unoccupied environment;

(ii) ***Setup and positioning instructions***; and

(iii) Information regarding ***material compatibility***.

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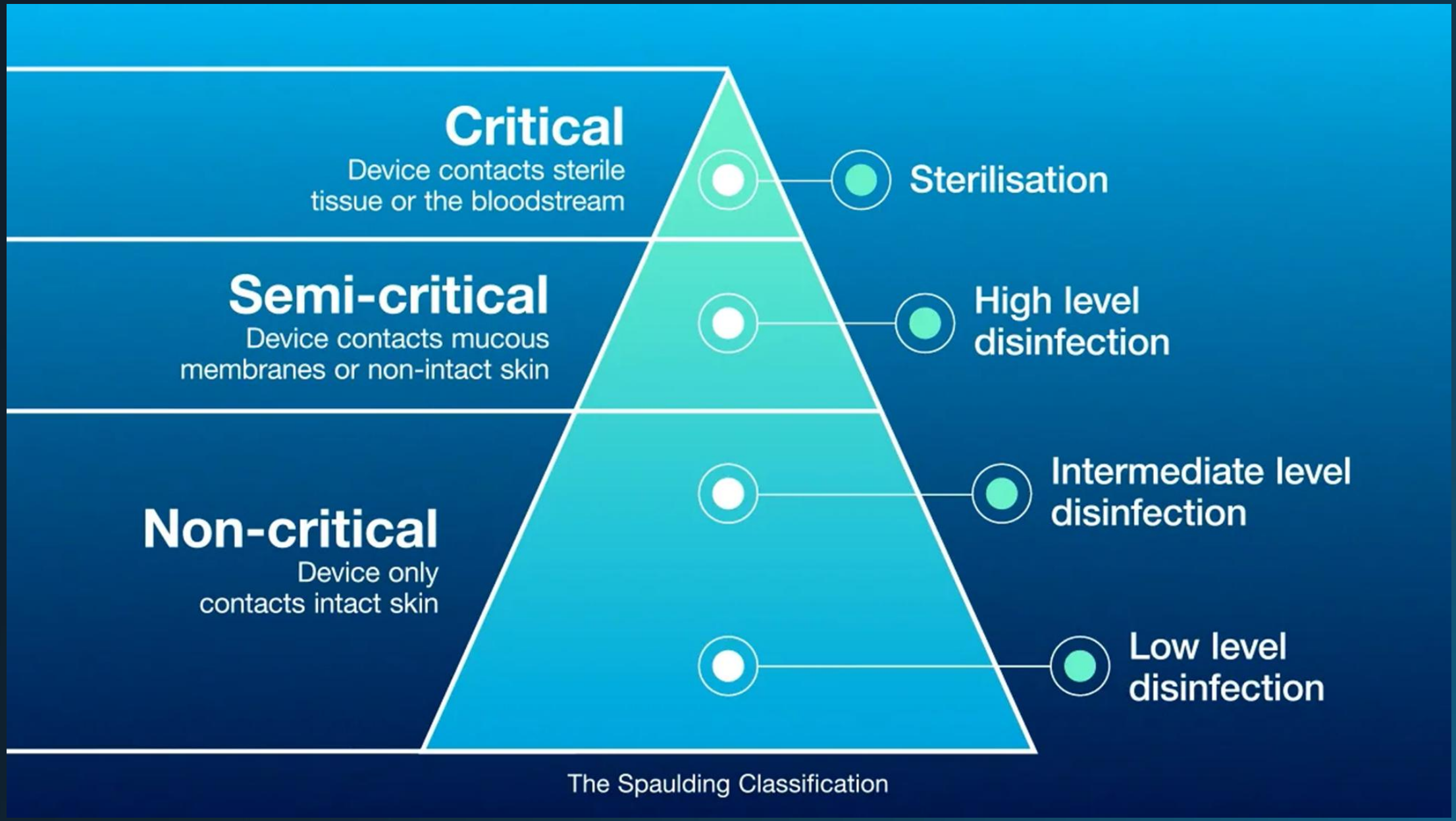

Critical
Device contacts sterile tissue or the bloodstream
Sterilisation
Semi-critical
Device contacts mucous membranes or non-intact skin
High level disinfection
Intermediate level disinfection
Non-critical
Device only contacts intact skin
Low level disinfection
The Spaulding Classification

UV-C MICROBIAL REDUCTION FACTORS:

Shadows

Time

Distance

Dose

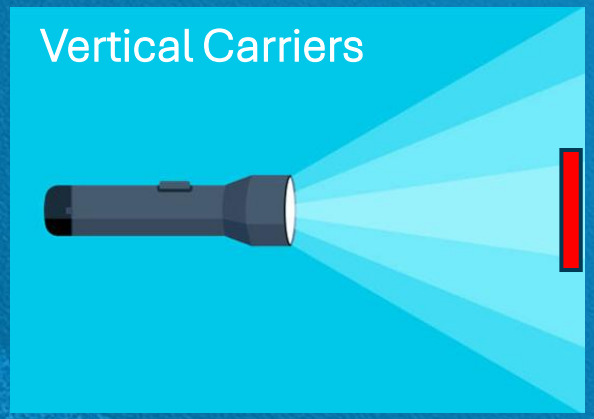
Labor

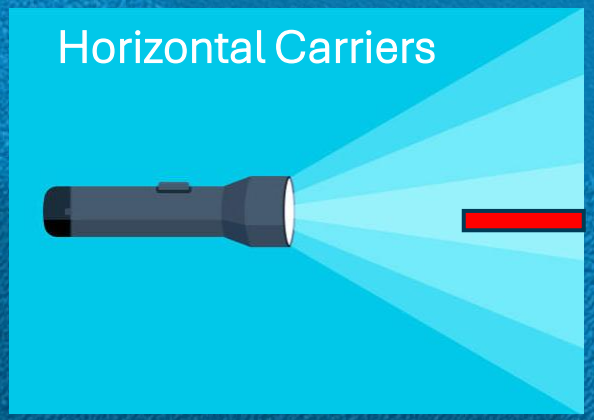
Orientation

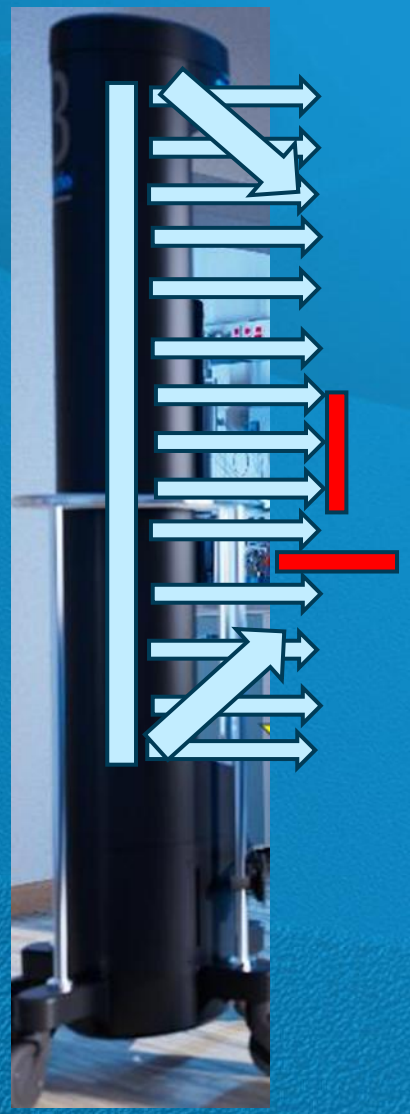
surfacide®
UV technology

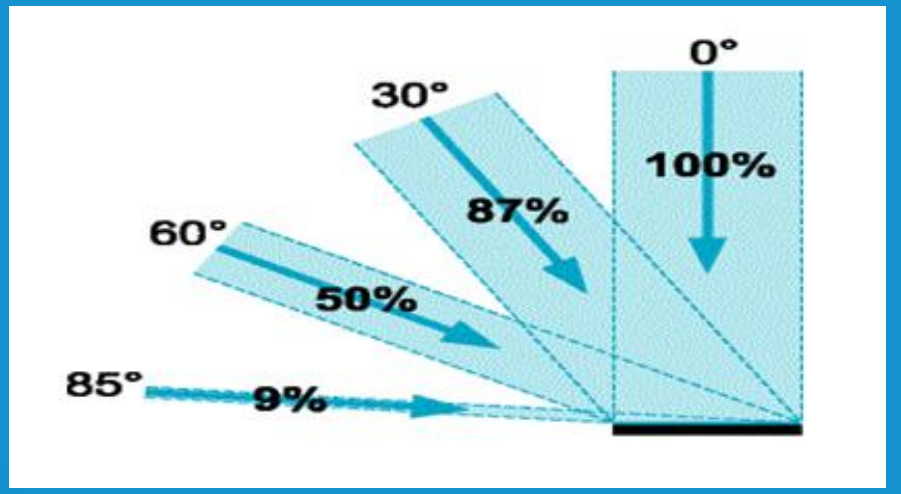
HORIZONTAL SURFACES: LAMBERT'S COSINE LAW

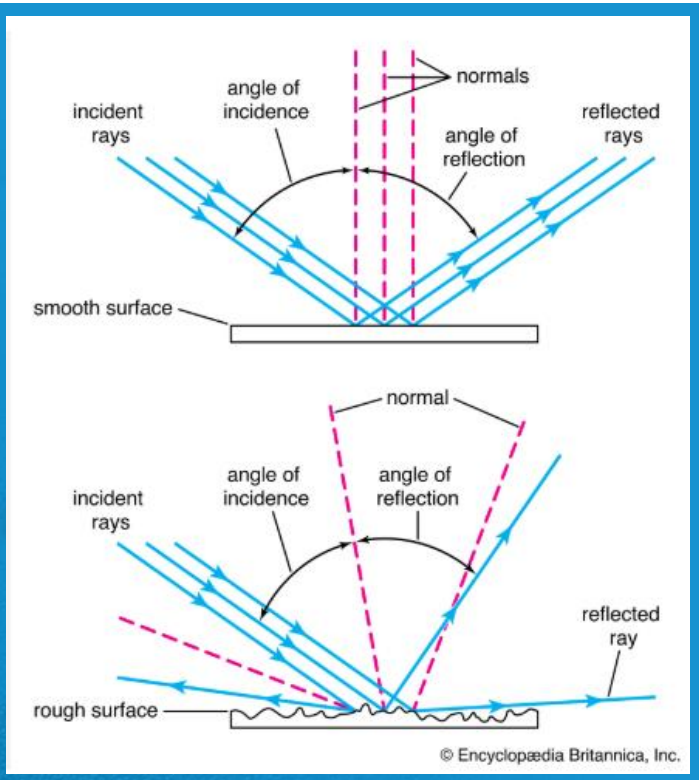
Angle of Incidence





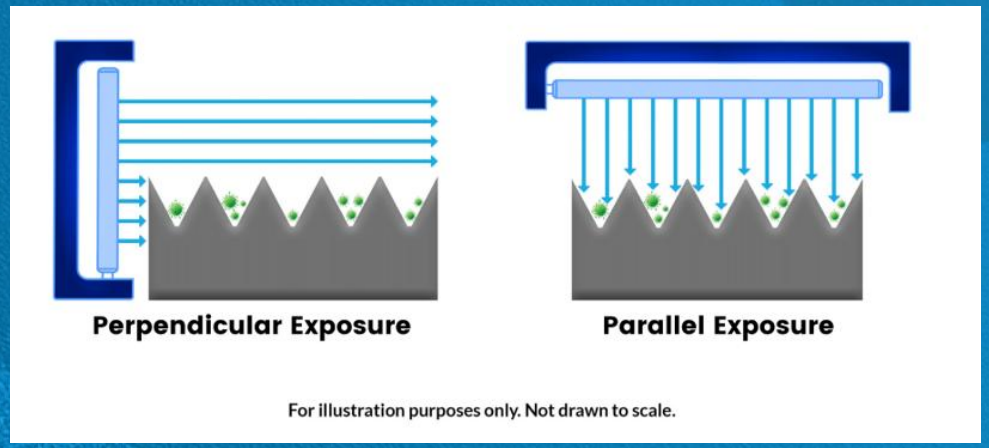






ORIENTATION TO SURFACES

Angle of Incidence



- Most UVC systems are upright with vertical lamps.
- More surfaces are horizontal than vertical in healthcare.
- Almost all UVC studies are for vertical surfaces. Easier for vertical lamps.
- It takes far more time to deliver UVC dose to horizontal surfaces.

				HORIZONTAL	VERTICAL
Configuration	**Description**	**Level**	**Target Organisms**	**Dose Requirement ($mJ/cm^{2)}$**	**Dose Requirement ($mJ/cm^{2)}$**
2	360° General Use; 3 ft. Distance (radius)	1	Vegetative Bacteria	300	<100
	1, 2 or 3 emitters	2	*C. diff (spore)*	1300	450

Dose in mJ/cm^2 Requirement: 4-log inactivation on horizotal surfaces.

Vegetative Bacteria: Included: *Psudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Klebsiella pneumoniae and Enterobacter cloacae*

UV-C MISINFORMATION:

The UV-C disinfection robot is listed with EPA as a pesticide device under EPA Est. No: 95582-DNK-1 and certified by the PMRA in accordance with section 7 of the Pest Control Products Act (PCPA) under Registration No. 34534.

Declaration Overview

Steriliz
SMARTER LIGHT

RD UVC RD-Fx UVC

August 2, 2024

Re: FDA information for use of UV-C equipment and systems in a hospital or healthcare facility.

To whom it may concern,

Recently, Steriliz LLC, the manufacturer of the RD Family of UV-C Disinfectors, has learned a certain competitor began circulating false information regarding the use of UV-C disinfection equipment and systems in U.S. Hospitals and healthcare facilities. We have been told by some of our customers that their hospital was told that they could not use any UV-C equipment other than that of our competitor because the competitor has received De Novo FDA approval. And our customers were also told that the competitor represented that their pathogen reduction times have been validated by the FDA.

Please see the attached email from Steriliz to the FDA, and their response. The competitor has grossly misrepresented the facts.

According to the FDA response, if you already have ANY UV-C equipment and/or systems in your hospital, including products made by our company, you may continue to use them without violating FDA regulations. And, your hospital and healthcare organization may continue to purchase and use ANY UV-C equipment and/or systems, including products made by our company, without violating FDA regulations.

Also, please be advised that Steriliz is in the process of 510K review by the FDA. We expect to have clearance in the near future.

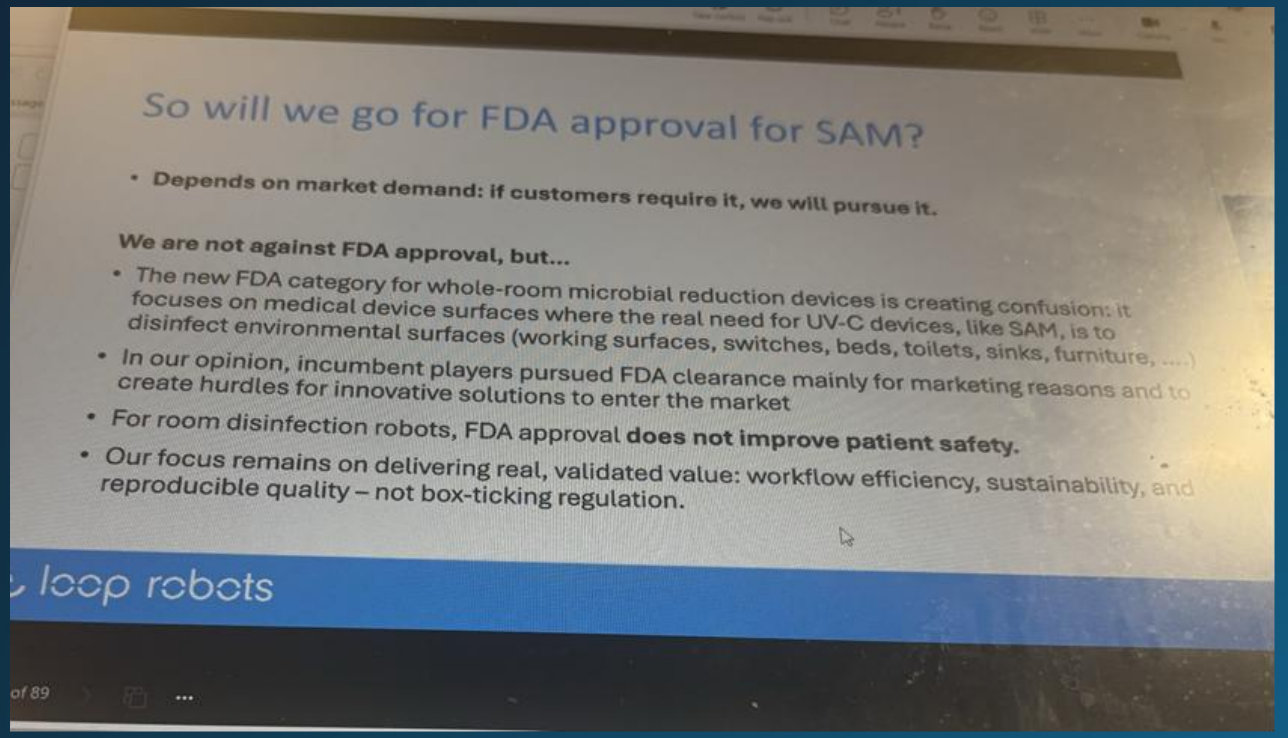
We hope this helps clarify the truth about using UV-C disinfection equipment and systems in your hospitals and healthcare organization.

Please feel free to contact me at any time to discuss.

Sincerely,

Samuel R. Trapani
CEO/President
Steriliz LLC
585-415-5411

Steriliz, LLC 2580 Baird Road Penfield, NY 14526 www.RDUVC.com



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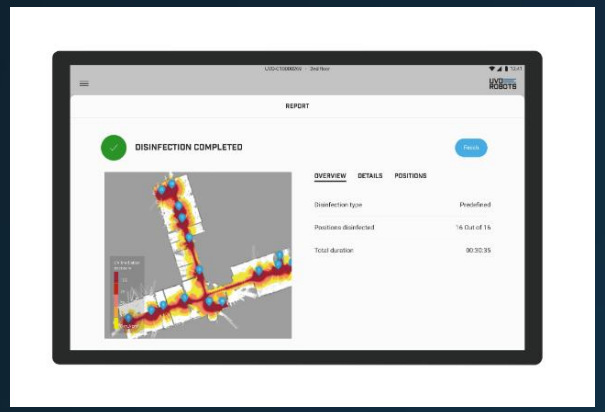
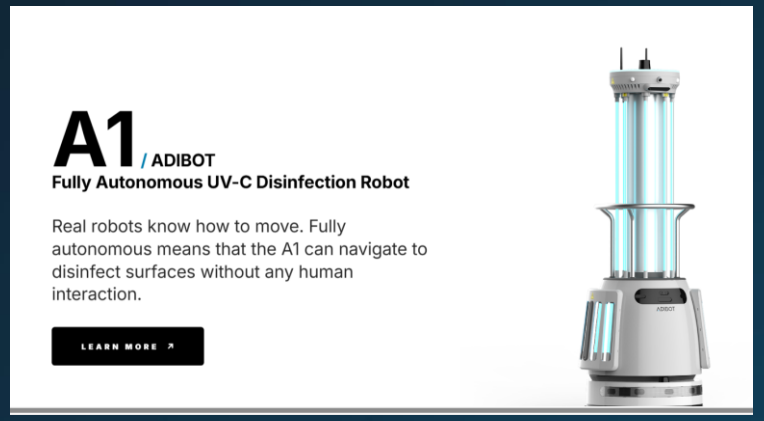
AUTONOMUS UV-C ROBOTS:



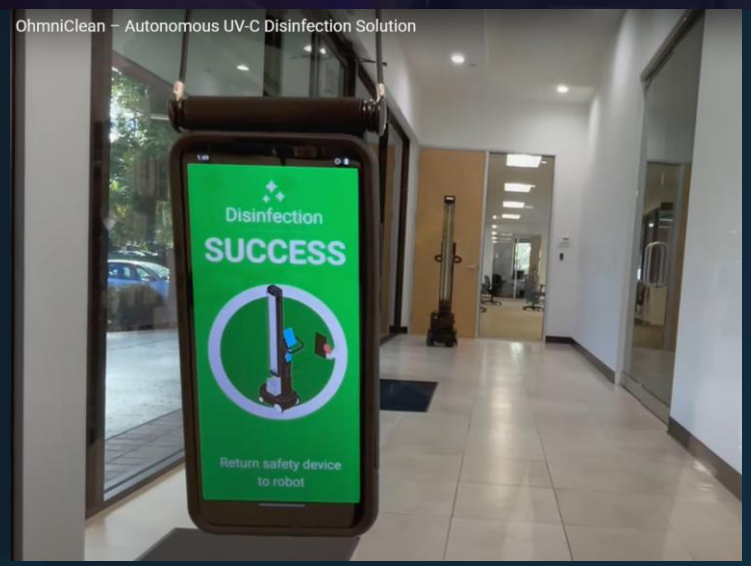


OHMNILABS

Powerful Disinfection Robot for Safer, Healthier Spaces

Elevate your UV disinfection with OhmniClean. This autonomous UV disinfection robot utilizes UV-C light to eliminate 99.99% of pathogens. Fast & effective, our UV disinfection system also yields considerable long-term costs savings.

FIND OUT MORE



"disinfection is not just enhanced…drives itself around the room…leaving no spot untouched…delivers thorough disinfection effortlessly and swiftly by completing the process two times faster than stationary devices…."

OHMNILABS

OhmniClean | OhmniCare | Company | Resources | Demo

The Autonomous Disinfection Robot Advantage

Thorough Disinfection in Significantly Less Time

Not all sanitizing robots are the same. See how much time is saved by choosing an autonomous solution instead of a manual disinfection system.

Disinfect Large Spaces in a Single Cycle

Due to its autonomous driving, OhmniClean can disinfect spaces both large and small with the same amount of effort from cleaning staff.

Eliminate Shadowing & Leave Zero Missed Surfaces

Unlike manual emitters, OhmniClean gets up close to all sides of an object, ensuring every space is thoroughly disinfected.

MANUFACTURER PERPSECTIVE:

MARKET CONFUSION:

- Manufacturers: Promotion/ False Claims
- EVS: End Users: Hospitals etc.
- Performance:
  - Time:
  - Distance
  - Dose
  - Orientation
  - Lack of Recognized Testing Standards

ENFORCEMENT:

- Explicit & implicit Promotion & Misbranding: Aggressive continued promotion of unapproved devices.
- EPA Pesticide Devices: Non healthcare

“UNCHARTERED WATERS”:

- “Whole Room”: Conflicting Terminology
- “Microbial Reduction”: an undefined term and previously unestablished log-reduction.
- Orientation/ Angle of Incidence: 3-6 x exposure time
- Microbiology: Variability and controlled parameters.

THANK YOU

Questions/Comments

Jeffry D. Veenhuis
President & CEO
Surfacide Manufacturing Inc.
jveenhuis@surfacidemfg.com