

**DE NOVO CLASSIFICATION REQUEST FOR
LIGHTSTRIKE+**

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 880.6510

CLASSIFICATION: Class II

PRODUCT CODE: QXJ

BACKGROUND

DEVICE NAME: LightStrike+

SUBMISSION NUMBER: DEN230007

DATE DE NOVO RECEIVED: February 01, 2023

SPONSOR INFORMATION:

Xenex Disinfection Services, Inc.
1074 Arion Circle\
Suite 116
San Antonio, TX 78216 USA

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.

LIMITATIONS

Limitations on device use are provided in the Instructions for Use Manual:

Warnings and Precautions

- do not use the device for microbial reduction of the critical or semi-critical surfaces of medical devices.
- do not use the device for microbial reduction of food or water.
- do not use the device for microbial reduction of a human or animal body or corresponding bodily fluids.
- not indicated for use in occupied rooms, areas, and spaces.
- follow unit setup and positioning instructions.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS

DEVICE DESCRIPTION

LightStrike+ is a system that emits UV germicidal light to reduce the microbial load present on non-porous, non-critical medical device surfaces in healthcare environments, after manual cleaning and disinfection practices. Designed for microbial reduction cycles, the system will achieve the labeled log reductions through the utilization of Xenon lamp technology for the generation of UV germicidal light in the system's intended use environments. It is designed to be moved to targeted locations within a facility. The graphical user interface allows operators (trained cleaning staff) to select preprogrammed rooms and their associated protocols for cycle execution. The system is for use in unoccupied areas and includes design and redundant safety features to help prevent accidental exposure to the UV light.



System Component	Function Summary
Robot	Generates UV light for whole room microbial reduction
Xenon Lamp	Xenon gas lamp that emits germicidal UV at wavelengths from 240 to 315nm when pulsed by the robot. The lamp is stored inside of the robot and rises to deliver the UV light
User Interface	Includes a room guide to allow the user to select the room where LightStrike+ will be used
	Cycle times are preprogrammed for each room and downloaded to the robot over wireless communications
	When a room is selected, the microbial reduction cycle will start once the physical button above the user interface screen is pressed and the robot senses the operator has exited the room
	The microbial reduction cycle will automatically stop when the cycle time countdown expires
Tethered Motion Detection Cone	Safety feature to help prevent inadvertent UV exposure to anyone entering the room while a cycle is active
	Placed inside the room/area where LightStrike+ will be used, facing the entry door
	Detects motion from the entry door to a room during a cycle and signals the robot to terminate the microbial reduction cycle when motion is sensed
Remote Status/Stop Cone	Feature to help prevent users from entering an area during a microbial reduction cycle. The cone serves as an indicator that LightStrike+ is in use within a room/area.
	Located outside the entrance of the room where LightStrike+ is in use
	Includes a feature to allow the user to terminate a cycle from outside the room
	Provides a visual countdown to indicate how much time is remaining in an ongoing microbial reduction cycle
	Provides warning to indicate that an individual should not enter the room during an ongoing cycle
	Once countdown expires, it provides a visual cue that it is safe to enter the room
Handle	Used to wheel and position the robot in the area where LightStrike+ will be used
	Can be pulled/pushed from both sides
Door Placard	Warning sign that adheres to the door exterior to indicate that LightStrike+ is being used in the Room/Area

SUMMARY OF BENCH STUDIES

REPROCESSING, STERILITY AND SHELF-LIFE

The LightStrike+ does not require reprocessing and sterility. The LightStrike+ does not have a labeled shelf life; device performance is not adversely affected by aging or

storage. Built-in design features monitor when the lamp is nearing the end of its usable life and prevent use of the device at that point.

BIOCOMPATIBILITY

The LightStrike+ uses a Xenon gas flash lamp to produce pulsed broad-spectrum germicidal UV light that reduces microbial load on non-porous, non-critical medical device surfaces in the whole room, for a period of time, after the room has been manual cleaned and disinfected. The operation occurs only if the room is unoccupied.

Testing was conducted to demonstrate that the operation of LightStrike+ generates Ozone at concentration levels that are below the maximum acceptable level of ozone in medical devices, according to 21 CFR 801.415, and is without an appreciable risk of deleterious effects. Additionally, test results demonstrate that the levels of toxic chemicals (other than ozone) generated during the use of LightStrike+ that would be safe for users/patients following the completion of the UV microbial reduction cycle are either below the safe exposure limit or will dissipate to safe levels when a user enters the room after the completion of the cycle.

Specifically, the concentrations of Carbon monoxide (CO), Carbon dioxide (CO₂), Nitric oxide (NO) and Nitrogen dioxide (NO₂) are well below the safe exposure limits, per 29 CFR 1910.1000, after the use of the LightStrike+ device. Test results demonstrate that there is a very low probability for the generation of toxic levels of Hydroxyl radical, singlet oxygen, and superoxide anion radicals by the LightStrike+ device in an indoor healthcare environment due to the low energy of the photons compared to the required Bond Dissociation Energy and the lack of high levels of pollutants. This is also clear from the low concentration of gases such as Ozone, NO, and NO₂ which are generated from the secondary interaction of these species with other molecules. The small amount of the generated radicals will also decay to safe levels because of the extremely low half-life and high reactivity of the species before a user enters the room after a disinfection cycle.

SOFTWARE

The LightStrike+ Software System is a collection software that executes on the Brazos physical device and cloud-based platforms. The Software System includes both off-the-shelf software and software that is developed and maintained by Xenex. The Software System is composed of the Microbial Reduction Management System (MRMS), Device Interface, and Firmware Software Items. The MRMS Software Item runs on cloud-based platforms. The Device Interface and Firmware Software Items run on the LightStrike+ physical device.

The interfaces between the top-level Software Items are indicated in Figure 1. MRMS and the Device Interface communicate remotely through two TCP/IP based protocols, HTTPS and MQTT. The Device Interface and the Firmware communicate through a RS232 link using a custom communication protocol and over TCP/IP sockets. In addition

to the interfaces between Software Items in Figure 1, each Software Item includes some form of interface. The LightStrike+ Software System includes two distinct user types, Device Users and MRMS Users. Device Users are those users that are authorized to use the LightStrike+ physical device and interact with the Device Interface and Firmware Software Items. MRMS Users are those authorized to access the user interfaces of the MRMS Software Item. Adequate cybersecurity and software functionality were demonstrated according to FDA guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”.

The LightStrike+ controls the integrity of the software by limiting access to trusted users and ensuring trusted content through software controls as defined within the Cybersecurity System, according to FDA guidance document titled “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” (<https://www.fda.gov/media/86174/download>). The effectiveness of the software security controls is determined through a threat model - risk assessment. Xenex controls deployment of software updates as per change control and procedures within the Software Development Plan. All potential firmware and software updates are reviewed against the most recent versions of the SRS.

ELECTROMAGNETIC COMPATIBILITY & ELECTRICAL SAFETY

The LightStrike+ electrical safety is in conformance with IEC 60601-1-6, and the electromagnetic compatibility (EMC) is in accordance with IEC 60601-1-2.

PERFORMANCE TESTING – BENCH

The sponsor conducted the following performance tests to support that the device can achieve its intended use:

- Optimized Kill Curve testing were provided, determining the dosage required for LightStrike+ to achieve a 2-log reduction of select bacterial organisms.
- Bacteriostasis of Intended In-use Surfaces were provided to verify potential inherent bacteriostatic properties of surfaces intended for future In-use testing.
- Recovery validation testing were provided to verify expected effectiveness of microbial recovery methods used to verify microbial reduction system results in a simulated use environment.
- Simulated-use tests were provided, demonstrating microbial reduction on medical device surfaces, using the determined most UV resistant organism, achieving an average of 2-log reduction across all inoculated surfaces.
- Accelerated UV materials damage test were provided, to evaluate the impact of regular exposure to LightStrike+ with metallic and non-metallic materials commonly present in healthcare environments, including materials commonly used as medical device enclosures.
- Ozone tests were provided, to ensure that LightStrike+ users are safe, notwithstanding the very low concentration of ozone that is produced by the device as a byproduct of UV-C light emission (to which the user could be exposed), per 21 CFR 801.415 “Maximum acceptable level of ozone”. The levels

of toxic chemicals (other than ozone) generated during the use of LightStrike+ that would be safe for users/patients following the completion of the UV microbial reduction cycle were also tested, per 29 CFR 1910.1000.

- Photobiological safety of lamps and lamp system test were provided, to evaluate the safety of the lamp that emits UV light when the robot is in use, conducted using a new lamp, because the light intensity is at its maximum when the lamp is new and that represents the worst-case scenario, per IEC 62471 “Photobiological Safety of Lamps and Lamp Systems.

The device has been appropriately evaluated for performance on the bench, demonstrating that is capable to achieve a microbial reduction of 2-log. Materials damage testing results met ISO 4582, ASTM D256-10, and ASTM A370-22 requirements. Ozone generation levels were below 21 CFR 801.415 acceptance levels. Levels of toxic chemicals were below 29 CFR 1910.1000 acceptance levels. Photobiological safety of lamps and lamp system met IEC 62471 criteria.

LABELING

The labeling consists of a user manual, instructions for use, and packaging labels. The instructions for use include the indications for use, including the time to achieve a 2-log reduction; a description of the device, contraindications, warnings, precautions, including a door placard with caution signs advising “DO NOT ENTER” to be affixed on entry ways of rooms/areas, warns of possible UV exposure during operation and warns of risk group 3 UV light generated by device; and instructions for the safe use of the device.

Labeling for this device is in accordance with the special controls listed below.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a whole room microbial reduction device and the measures necessary to mitigate these risks.

Identified Risks to Health and Mitigation Measures

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

Risks to Health	Mitigation Measures
	Labeling
Interference with other devices	Electromagnetic compatibility testing Electrical safety testing Wireless coexistence testing Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the whole room microbial reduction device is subject to the following special controls:

- (1) 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.
- (2) Biocompatibility testing must demonstrate safe residual levels of chemicals on medical devices surfaces and/or gaseous byproducts in air.
- (3) Software verification, validation, and hazard analysis must be performed for any software components.
- (4) Performance data must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.
- (5) 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.

BENEFIT-RISK DETERMINATION

Risks:

The risks of the device are based on nonclinical laboratory (bench) studies described above.

Subject device is to be used in an unoccupied room. The only risk of injury is skin and eye damage resulting from exposure to dangerous light source, respiratory issues from exposure to

ozone, electrical shock and interference with other devices are mitigated with the performance testing, warnings, precautions, and special controls. Risk of device failure leading to microbial growth, increasing the risk of patient-to-patient cross contamination and study limitations, are mitigated with the performance testing, labeling, special controls, and the use as adjunct to manual cleaning and disinfection only.

Benefits:

The probable benefits of the device are based on nonclinical laboratory (bench) studies described above.

The LightStrike+ device demonstrated 2-log average reduction in simulated use testing using worst-case microorganisms. The device will be used as an adjunct to existing manual cleaning practices. LightStrike+ provides additional microbial reduction after manual cleaning and disinfection, strengthening the risk reduction of transmitting pathogens from one patient to the next, or between health care providers and patients. The magnitude of the clinical benefit (i.e., transmission reduction) has not been established based on the non-clinical testing provided by the sponsor. Data was robust for 2-log average reduction on medical device surfaces, in the simulated environment.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

Based on the performance testing provided (in particular, log reduction test, in a simulated-use test, optimized kill curve determination test, bacteriostasis test, microbial recovering test, biocompatibility test, material degradation test, ozone test, photobiological safety of lamps and lamp systems tests, and labeling), the sponsor has adequately supported that the subject device is a UV-C light microbial reduction device adjunctive to manual cleaning. This feature will provide an additional microbial reduction to surfaces that were previous cleaned and disinfected, helping to prevent cross contamination among patients and healthcare staff.

In conclusion, given the testing provided above, for the following indication statement:

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.

The probable benefits outweigh the probable risks for the LightStrike+. The device provides benefits and the risks can be mitigated using general controls and the identified special controls.

CONCLUSION

The De Novo request for the LightStrike+ is granted and the device is classified as follows:

Product Code: QXJ

Device Type: Whole room microbial reduction device

Regulation Number: 21 CFR 880.6510

Class: II